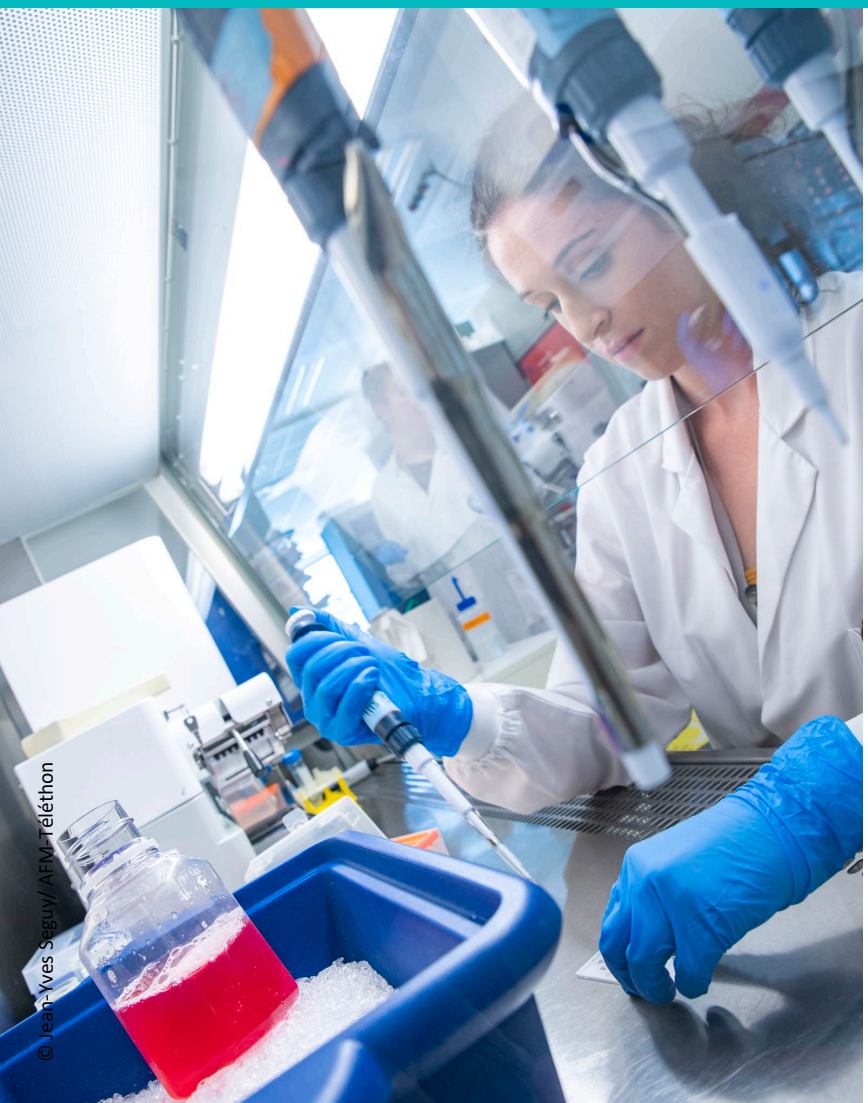
JUNE 2025

SAVOIR & COMPRENDRE
AVANCÉES DE LA RECHERCHE

Advances 2025 in myasthenia gravis



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This document, published to coincide with the AFM-Téléthon General Meeting 2025, presents a selection of myasthenia gravis research news stories from the past year (ongoing observational studies and clinical trials, scientific and medical publications...).

AFMTÉLÉTHON
INNOVER POUR GUÉRIR

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Myasthenia gravis

MG

Myasthenia gravis (MG) is an autoimmune disease. It is caused by immune system dysfunction which gives rise to a defect in the transmission of nerve impulses between nerves and muscle causing muscle weakness that fluctuates over time.

Common symptoms

- **Ocular myasthenia gravis** only affects the eye muscles. Symptoms include drooping of the upper eyelids (ptosis) and double vision (diplopia).
- **Generalised myasthenia gravis** also affects other parts of the body such as the arm, hand and leg muscles and/or the respiratory muscles and/or the neck, face and throat muscles.
- **Possible thymus abnormalities** such as an increase in the size of the thymus (hyperplasia) and thymoma (a tumour originating from the cells of the thymus).

Management and treatment

Cholinesterase inhibitors

- Inhibit an enzyme called acetylcholinesterase in order to improve the transmission of nerve impulses to muscles which make them contract
- Often less effective in anti-MuSK autoantibody positive myasthenia gravis
- Mestinon®, Mytelase®

Corticosteroids and immunosuppressants

- Reduce immune system activity
- Prednisone, azathioprine (Imurel®), mycophenolate mofetil (CellCept®), cyclosporin (Néoral®), tacrolimus (Prograf®)

Biological therapies

- Made from a biological source
- Modulate immune system activity (immunomodulators)
- Immunoglobulins, targeted therapies (rituximab (MabThera®), efgartigimod (Vyvgart®), ravulizumab (Ultomiris®), zilucoplan (Zilbrysq®), rozanolixizumab (Rystiggo®))

Plasmapheresis

- Uses a machine that filters blood and purifies it from substances such as autoantibodies
- Used in the event of severe symptoms

Thymectomy

- A surgery that consists of removing the thymus in order to eradicate the cells that take part in the autoimmune response
- Offered to those with anti-AChR autoantibodies, it is essential in cases of thymoma

In numbers

10 to 20 people in every 100,000 have myasthenia gravis (over 20,000 people in France)

Over 880 scientific articles published between April 2024 and April 2025 *(PubMed)*

112 clinical trials including **18** in France *(ClinicalTrials.gov 02/04/2025)*

What causes myasthenia gravis?

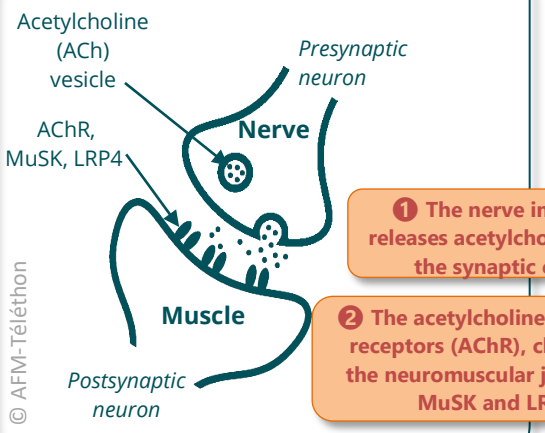
Genetic predisposition
+ Environmental factors
(infections, endocrine disruptors…)

→ **Immune system dysfunction**

↓

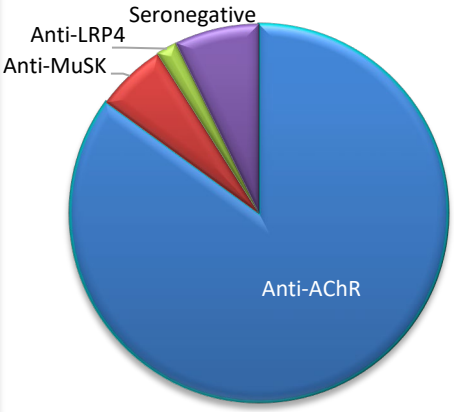
Autoimmune reaction with the production of **autoantibodies** against components of the neuromuscular junction *(acetylcholine receptor (AChR), muscle-specific tyrosine kinase (MuSK) protein, LRP4 protein…)*

Neuromuscular junction



1. The nerve impulse releases acetylcholine into the synaptic cleft
2. The acetylcholine binds to its receptors (AChR), clustered at the neuromuscular junction by MuSK and LRP4
3. The muscle contracts

Autoantibodies in myasthenia gravis



"Seronegative" = no anti-AChR, anti-MuSK or anti-LRP4 autoantibodies

Normal immune response

Immune system

↓ Production of antibodies against foreign antigens

↓ Destruction of foreign bodies

Viruses, bacteria…

Autoimmune reaction

Immune system

↓ Production of autoantibodies against self-antigens

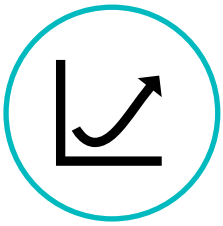
↓ Attack on parts of the body

Body's own cells

For more information on myasthenia gravis, please visit:
www.afm-telethon.fr/fr/fiches-maladies/myasthenie-auto-immune [page in French]

3 Highlights from the past 12 months

1 The boom in CAR-T cell clinical trials



At the crossroads of cell and gene therapies, CAR-T cells are used to destroy specific cells. Initially developed to target cancer cells, CAR-T cells are now being developed to destroy immune cells such as B cells which are involved in the production of antibodies, including autoantibodies. In June 2023, four CAR-T cell clinical trials in myasthenia gravis were underway or in preparation around the world. In 2025, there are 17, including one in France taking place in Lille and Paris.

2 New symptoms identified thanks to patients

Myasthenia gravis patients are being asked more and more about the manifestations of their disease, particularly in quality of life surveys, and their opinions are being taking into account more frequently. This has resulted in the emergence of non-motor symptoms, such as urinary and sexual problems, fatigue, anxiety, pain and sleep disorders, which were not talked about a few years ago. However, much progress remains to be made with regard to routine screening for these problems during consultations, but also in terms of treatment.

"Mon SELFIM" helps you communicate your symptoms!
Myasthenia gravis is a disease that fluctuates over time. In these types of conditions, it is difficult for doctors to track everything that has happened in the periods in between consultations. The self-administered questionnaire "Mon SELFIM" helps to do this. Created with the help of neurologists, nurses and patient representatives (including from AFM-Téléthon), this tool allows patients to record their symptoms at their own pace and in their own words, and their impact on their daily lives. You can fill it in online, or print it out and take it with you to your next consultation.
Find out more from the Groupe d'intérêt Myasthénies AFM-Téléthon [page in French]

3 More and more late diagnoses

The prevalence of myasthenia gravis is increasing amongst older adults in France and in many other countries around the world. It is particularly high in men over the age of 70, even though myasthenia gravis was previously described as a young woman's disease. To explain this phenomenon, doctors cite improvements in the diagnosis of the disease, including better recognition of atypical forms (isolated ocular signs, swallowing difficulties...) which are sometimes seen in the elderly. They also cite the aging of the population, as well as that of the immune system (immunosenescence) which favours the development of autoimmune diseases.
Keovilayhong S et al. Rev Neurol (Paris). 2024
Bril V et al. J Neurol Sci. 2025

Further progress is needed

Room for improvement

Despite the major advances made in treatment in recent years, myasthenia gravis continues to have a sometimes significant impact on everyday life, and therefore on quality of life. In addition, current drugs remain ineffective or cause too many adverse drug reactions in a significant proportion of myasthenia gravis patients. Myasthenia gravis is still a serious disease, associated with a mortality rate higher than that of the general population, including in France.

Indicators of poor management

Between 2013 and 2020, 6,354 people in France made their first health insurance claim for myasthenia gravis-related care. A third of these patients were hospitalised at least once in intensive care, 44% received intravenous immunoglobulin therapy (IVIg) and nearly 7% underwent plasmapheresis, usually within a year of being diagnosed with the disease. These are all indicators of poor disease management by treatment.

Although the situation improved after the first year, nearly 8% of the patients continued to be admitted to intensive care and approximately 5% received IVIg every year during the remaining follow-up period. Finally, more than half of the participants received no immunosuppressants during the study.

Attarian S et al. Eur J Neurol. 2025

Two approaches

Two main paths are taken to improve treatments in myasthenia gravis.

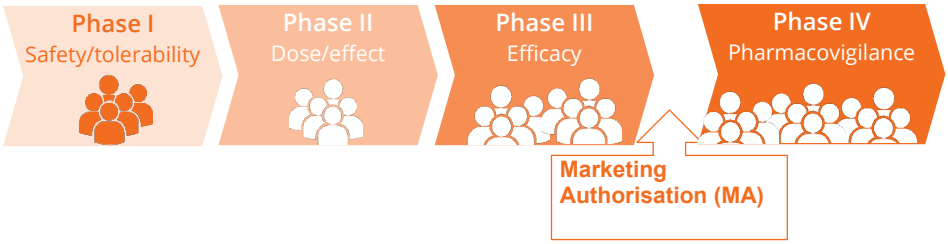
- **Enhancing "traditional" treatments** (drugs, surgery...) with the aim of improving the benefit / risk ratio of side effects and specifying the scope of each one (when, for which form of the disease...).
- **Developing innovative treatments** which act more selectively on the immune system and therefore are potentially more effective, better tolerated and act faster than classic immunosuppressants.

The key role of trials

Clinical trials consist of assessing a potential treatment (drug candidate, medical device...) in order to ensure that it is well tolerated and effective in treating a disease. The product or device is tested during successive phases (I, II, III, IV) which each answer specific questions such as: is it well tolerated? What is the optimal dose? Is it effective and according to what criteria?

After a treatment has received regulatory approval, it is then used in real life and continues to be monitored in order to refine knowledge and identify any unexpected or serious side effects that may occur.

Les essais cliniques en pratique [Clinical trials explained]



Drug trials in France

Drug	Approach	Phase	Recruitment
CC-97540 *(Breakfree-2)* 120 participants	CAR-T cells	I	Recruiting
NMD670 *(SYNAPSE-MG trial)* 84 participants	Anti-ClC-1	II	Recruiting
Nipocalimab 196 participants	Anti-FcRn	III	Recruiting
Efgartigimod two regimens *(ADAPT NXT trial)* 69 participants	Anti-FcRn	III	Not recruiting
Efgartigimod in children *(ADAPT Jr SC trial)* 12 participants	Anti-FcRn	II/III	Recruiting
Efgartigimod in children *(ADAPT Jr trial)* 12 participants	Anti-FcRn	II/III	Recruiting
DNTH103 *(MAGIC trial)* 60 participants	Anti-C1	II	Recruiting
Gefurulimab or ALXN1720 *(PREVAIL trial)* 260 participants	Anti-C5	III	Not recruiting
Ravulizumab in children 12 participants	Anti-C5	III	Recruiting
Pozelimab +/- **Cemdisiran** (*NIMBLE trial*) 335 participants	Anti-C5	III	Recruiting
Zilucoplan (*RAISE-XT trial*) 200 participants	Anti-C5	III	Not recruiting
Inebilizumab *(MINT trial)* 238 participants	Anti-CD19	III	Not recruiting
Rituximab + corticosteroids *(IMCOMG trial)* 128 participants	Anti-CD20	III	Not yet recruiting

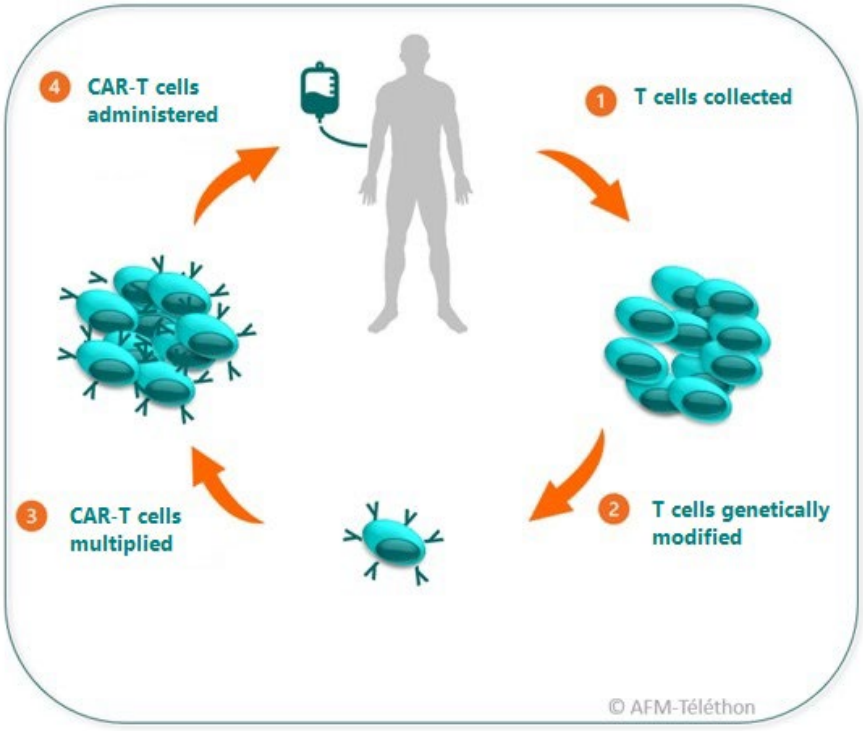
Innovative treatments in trials

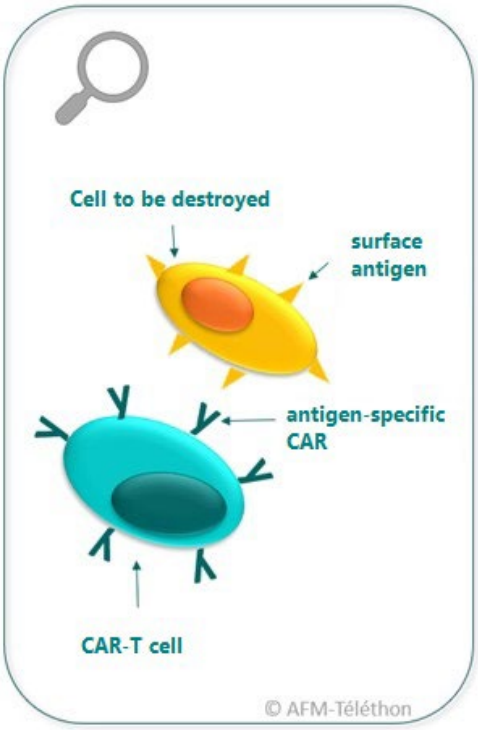
CAR-T cells - a cell and gene therapy

CAR-T cells are T cells (a type of white blood cell) that are able to recognise and destroy specific cells such as cancer cells or cells infected by a microorganism.

▪ These T cells, which are usually collected from the patient to be treated (autologous cells), are genetically modified in a laboratory (gene therapy) to make them capable of recognising specific antigens that are present on the surface of the cells to be destroyed.
Once modified in this way, the T cells become CAR-T cells (CAR stands for chimeric antigen receptor). They will then be injected into the patient (cell therapy), usually after very powerful immunosuppressive treatment (chemotherapy) has been administered to weaken the immune system and reduce the number of the natural lymphocytes in the body.

***T cells** are white blood cells that specialise in certain immune reactions. There are several different types of T cells, each one with a specific function. Unlike B cells, T cells do not secrete antibodies.*





First oncology, then immunology

This therapy was originally developed to treat blood cancers, with six drugs currently approved in France. Over 12,200 people in Europe have already been treated with CAR-T cells.

▪ For several years, CAR-T cells have also been studied in severe forms (refractory to the usual treatments) of various autoimmune diseases. The objective is to destroy immune cells that react abnormally to components of the body and cause the manifestations of the disease.

Of the nearly 1,200 CAR-T cell clinical trials underway or in preparation around the world at the start of 2025, more than 10% are not in the field of oncology, with autoimmune diseases such as lupus, scleroderma, myositis and myasthenia gravis taking centre stage.

Did you know?

AFM-Téléthon and CAR-T cell research

With the support of AFM-Téléthon, several teams of researchers in France worked on using CAR-T cells to treat various neuromuscular diseases, including:
- Prof. Olivier Boyer's team (CHU Rouen [Rouen University Hospital]) on developing CAR-T cells in immune-mediated necrotising myopathy;
- Inès Barthélemy's team (École Nationale Vétérinaire d'Alfort [National Veterinary School of Alfort]) on creating CAR-T cells to tackle fibrosis in Duchenne muscular dystrophy.

Various cases of CAR T-cell therapy used in autoimmune diseases published so far are promising, with big improvements seen in terms of symptoms and autoantibodies.

- Producing CAR-T cells is still a long and expressive process, and questions about their optimal use remain unanswered. How long will remission last and will the treatment need to be repeated? What's the best indication? After trying several other treatments or at an earlier stage? What about their safety, including possible long-term risks? The numerous clinical trials currently taking place should provide some answers.

Rampotas A et al. Bone Marrow Transplant. 2025 *Brittain G et al. Ann Neurol. 2024*
Haghikia A et al. Lancet Neurol. 2024 *Ismail FS et al. JAMA Neurol. 2025*

***Autoantibodies** are antibodies that react with parts of an individual's own body, such as the neuromuscular junction.*

B cells - at the centre of the autoimmune reaction

In autoimmune diseases, the immune system's attack on certain parts of the body damages tissue (muscle, nerves...). B cells can be involved in causing this damage in two ways:
- directly, by producing autoantibodies that attack target tissue (these autoantibodies being produced by plasma cells - daughter cells of B cells),
- indirectly, by presenting target tissue antigens to T cells as if they were foreign substances, causing them to be destroyed.

CAR-T cells being developed in myasthenia gravis target specific elements of B cells with the aim of destroying them.

A record number of trials

17 CAR-T cell clinical trials in myasthenia gravis are currently underway or in preparation around the world, involving a total of nearly 600 participants. The different types of cells being studied are distinguished by the surface antigen that they target:

- CD19, a protein found on the surface of B cells;
- BCMA (B-cell maturation antigen), present on the surface of plasma cells;
- CD20, a protein present on the surface of B cells. Certain drugs (such as rituximab) also target CD20;
- CD22, a protein found on the surface of B cells;
- a surface antigen specific to B cells that are responsible for the production of anti-MuSK autoantibodies.

Some CAR-T cells have several targets (CD19 and BCMA, CD20 and BMCA, or CD19, 20 and 22). All of these cell types are currently being evaluated in adults (over 18 years old) with a refractory form of generalised myasthenia gravis (seronegative or seropositive).

"Universal" CAR-T cell therapy

One of the products being evaluated in myasthenia gravis in China (trial NCT06485232) sets itself apart through its design - T cells are not taken from the patient but from healthy donors. The CAR-T cells are then developed in such a way so as to not be rejected when administered to the patient, that is, by removing what could be recognised by the patient's immune system from their surface (HLA markers).

These are referred to as "universal" CAR-T cells. Researchers hope to overcome the difficulties involved in making CAR-T cells, producing more of them and in a quicker and more cost-effective way.

*An "**NCT**" number is an identification number assigned to each clinical trial on ClinicalTrials.gov, the most comprehensive clinical trials database in the world which is operated by the National Institutes of Health (NIH). Clicking on this number in the text will open the corresponding trial's description page.*

Descartes-08

Descartes-08 is a CAR-T cell therapy created by Cartesian Therapeutics which is in the furthest stage of development in clinical trials (phase III announced) for myasthenia gravis. It has been granted orphan drug designation by the American health authorities for myasthenia gravis. It is characterised by its use of RNA instead of DNA.

In a laboratory, an RNA molecule is introduced into T cells taken from the patient to be treated which codes for the production of a receptor that will allow the T cells to bind to BCMA in order to destroy plasma cells. The specificities of obtaining the CAR-T cells used in this therapy mean that prior strong immunosuppressive treatment is not necessary, which reduces the risk of adverse effects.

*The **"orphan drug"** designation is applied to drug candidates (whose efficacy has not yet been demonstrated) in rare diseases, with the aim of facilitating the various stages of their development.*

Preliminary results confirmed

Launched in 2019, the phase II MG-001 trial evaluated Descartes-08, initially in an open-label format, then vs placebo, in 36 adults with generalised myasthenia gravis. At the end of 2024, the pharmaceutical company Cartesian updated the preliminary and partial results, confirming:

- a significant improvement in the symptoms of the disease (an average reduction of 5.5 points on the MG-ADL scale after four months) and its durable nature, with maintenance of clinically significant efficacy in the vast majority of participants who were able to be assessed after one year of treatment,
- that Descartes-08 was well tolerated, with side effects that were temporary and usually mild (headaches, nausea...), and no increase in the rate of infections or the occurrence of known adverse drug reactions for CAR-T cell therapies used to treat cancer (cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome).

Three participants in the open-label phase received a second treatment cycle of Descartes-08 with positive results.

Cartesian Therapeutics, press release 3 December 2024

*A **placebo** is a product whose appearance is identical to a particular medicine but does not contain any active substances. In a clinical trial, a placebo is used to measure the true action of a medicine by comparing the effects of the medicine (which contains the active substance) to those of the placebo.*

*An **open-label trial** is a clinical trial in which the doctors and participants know what treatment is being administered.*

Cartesian Therapeutics announced the launch of a phase III trial called AURORA (NCT06799247) in 2025. It will include 100 adults with anti-AChR autoantibody positive generalised myasthenia gravis which is severe despite immunosuppressive treatment. This trial will compare the efficacy, safety and tolerability of Descartes-08 vs placebo. The participating countries are not yet known.

CAAR-T cells for anti-MuSK autoantibodies

Phase I
Safety/tolerability

The pharmaceutical company Cabaletta Bio is developing MuSK-CAAR-T cells (with two "As" for "AutoAntibody") which bind specifically to B cells that are reactive to the MuSK protein. They showed their ability to induce complete and durable remission of anti-MuSK autoantibody positive myasthenia gravis in models of the disease. Their efficacy, safety and

tolerability are being evaluated in a trial that is currently taking place in the United States (NCT05451212). In the future, this specific approach could be applied to all autoimmune diseases for which the causative self-antigens have been identified.

Oh S et al. Nat Biotechnol. 2023

In France

The CD19-targeted CAR-T cells **CC-97540** are being developed by Juno Therapeutics, a Bristol-Myers Squibb company. They are being studied in two phase I clinical trials in which France is participating.

Phase I
Safety/tolerability

The Breakfree-1 trial (NCT05869955) in lupus, scleroderma and inflammatory myopathies (myositis).

Encouraging preliminary results concerning four participants in this trial (all lupus patients) were shared during the annual ACR Convergence conference at the end of 2024.

Schett G et al. ACR convergence 2024

The Breakfree-2 trial in multiple sclerosis and myasthenia gravis.

The myasthenia gravis patients must be positive for anti-AChR or anti-MuSK autoantibodies and have a generalised form of the disease which remains active despite at least two immune-targeted treatments (corticosteroids, immunosuppressants). The participants must have had a thymectomy. They will all receive an infusion of CAR-T cells (open-label trial) preceded by immunosuppressive chemotherapy (fludarabine, cyclophosphamide). The trial is taking place in 37 investigator sites around the world, including one in Lille and one in Paris.

Phase I
Safety/tolerability

Breakfree-2 trial

France and abroad	120 (18 to 60 years old)	Recruiting	March 2024 – July 2027 2 years of follow-up

NCT06220201

Stem cell therapy

Stem cells *possess both the ability to multiply to produce identical new stem cells (self-renewal) and the ability to give rise, under specific conditions, to differentiated cells (blood cells, liver cells, muscle cells….).*

How does it work?

Receiving a "haematopoietic" stem cell transplantation can also help "reset" the immune system in various autoimmune diseases. This treatment enables new immune cells to be produced which are tolerant to the parts of the body in which they are injected. Today, doctors use this technique in myasthenia gravis, particularly in patients with very limited treatment options. According to data in the European Society for Blood and Marrow Transplantation Registry, of the 4,317 people who have received a stem cell transplantation for an autoimmune disease in Europe since 1997, only 11 of them had myasthenia gravis.

Greco R et al. EBMT registry 2024

In January 2025, a Canadian team published their experiences with autologous stem cell transplantations in anti-AChR and anti-MuSK autoantibody positive myasthenia gravis. Twenty-one patients received one between 2001 to 2022, two to 22 years after being diagnosed with the disease. All of the patients had a severe form of myasthenia gravis despite

having received various different treatments (corticosteroids, rituximab, azathioprine, immunoglobulins).

▪ Of the 18 evaluable patients, 16 had no symptoms of myasthenia gravis or minimal manifestations without specific treatment (which was able to be stopped 0 to 5.6 years after receiving the transplant). They remained stable thereafter.
The other two evaluable patients experienced a significant improvement in their disease, but had to continue using some immunosuppressant-based and/or cholinesterase inhibitor-based treatment.

▪ Of the three non-evaluable patients, two died within 100 days of the transplant due to a complication (respiratory failure and serious infection) linked to the transplant, including the preparatory treatments that it requires.
This figure is not surprising given the seriousness of the situation for transplant candidates (severe form of myasthenia gravis, comorbidities of successive immunosuppressive treatments...), and their mortality rate without a transplant might not have been much different.
Beland B et al. Ann Clin Transl Neurol. 2025

Minimal manifestation status *(MMS) means that a patient has no symptoms or functional limitations from myasthenia gravis. However, there is still some weakness in certain muscles upon examination, therefore it is not considered remission.*

A trial in the United States which completed recruitment in 2024 is evaluating the safety and efficacy of **autologous stem cell** transplantation preceded by the administration of chemotherapy and antithymocyte globulin (an antirejection drug). The participants have various conditions, including myasthenia gravis.

Autologous stem cell transplantation

Phase II
Dose/effect

United States	53 (up to 71 years old)	Not recruiting	June 2008 – Jan 2030 5 years of follow-up

NCT00716066

Desensitisation to the components of the neuromuscular junction

How does it work?
Based on an idea comparable to that of becoming desensitised to an allergen, several teams are currently attempting to induce self-tolerance in myasthenia gravis (the body would become tolerant to the components of the neuromuscular junction). This strategy is now in the clinical trial phase.

*The **neuromuscular junction** is the site of communication between the nerve through which the contraction signal (nerve impulse) arrives and the muscle that contracts due to the nerve impulse.*

Developed by COUR Pharmaceuticals, **CNP-106** consists of AChR fragments encapsulated by nanoparticles. A placebo-controlled trial is evaluating it in adults who are positive for anti-AChR autoantibodies, with two infusions administered one week apart, and sometimes a third infusion three months later.
Recruitment for this trial started in October 2024 according to the pharmaceutical company, which is also developing the same type of approach in type 1 diabetes and coeliac disease.
G Brew S et al. BMJ Neurol Open. 2024
COUR Pharmaceuticals. Press release 30 October 2024

Phase I
Safety/tolerability

Phase II
Dose/effect

Placebo-controlled CNP-106 trial

United States

54
(18 to 75 years old)

Recruiting

May 2024 – August 2026
6 months of follow-up

NCT06106672

The rise of targeted therapies

No fewer than 17 clinical trials currently underway or in preparation around the world are evaluating treatments which each target a specific element (receptor, protein...) involved in autoimmunity. Most of these are antibodies or components of monoclonal antibodies (biological therapies).

- These targeted therapies are designed to modulate immune system activity in a more specific way than traditional immunosuppressants (which suppress the entire immune system).

They are often developed for several autoimmune diseases and are distinguished by their rapid onset of action (sometimes seen from the first week of treatment). Several of them have already obtained marketing authorisation or early access authorisation for myasthenia gravis.

Mechanism of action	Drug candidate
Anti-complement	• Cemdisiran (ALN-CC5) • DNTH103 • Eculizumab (Soliris®) • Gefurulimab (ALXN1720) • Iptacopan *NEW* • Pozelimab (Veopoz®) • Ravulizumab (Ultomiris®) • Zilucoplan (Zilbrysq®)
Anti-neonatal Fc receptor (anti-FcRn)	• Efgartigimod (Vyvgart®) • Nipocalimab (M281) • Rozanolixizumab (Rystiggo®)
Anti-CD19	• Inebilizumab (Uplizna®)
Anti-CD19 and anti-CD3	• Blinatumomab (Blincyto®) *NEW*
Anti-CD20	• Rituximab (MabThera®) • B007 *NEW*
Anti-BTK	• Remibrutinib (LOU064) *NEW*
Anti-BLyS and anti-APRIL	• Telitacicept (RC18)
Adenosine analogue	• Cladribine *NEW*
Anti-ClC-1	• NMD670 *NEW*

Marketing authorisation *(MA) enables a new drug to be sold. It is granted in France by the Agence nationale de sécurité des produits de Santé (French medicines agency) or, at a European level, by the European Commission, after consulting the European Medicines Agency. To be granted marketing authorisation, the pharmaceutical company must provide scientific data from the development phases, in particular from clinical trials. The decision is made based on safety, efficacy and quality*

Early access programmes *enable access to innovative drugs whose safety and efficacy are strongly presumed in a given indication, which must be a severe, rare or debilitating disease for which no appropriate treatment is available. The word "early" indicates that the drug has not yet obtained marketing authorisation (MA) or been made eligible for reimbursement from health insurers for this indication. The pharmaceutical company will then undertake to request this from the health authorities.*

www.has-sante.fr/ [page in French]

What, who for and when?

The respective role of these therapies in the treatment of myasthenia gravis is yet to be defined. What are their respective indications? Should they be combined to further improve their results? When is the best time to start them (as soon as the diagnosis has been made, in the event of a flare-up)? So many questions which should be answered by the clinical trials currently taking place.

Gwathmey KG et al. Muscle Nerve. 2024

▪ Currently, targeted therapies that have been granted either early access authorisation or marketing authorisation (MA) are generally used when more traditional drugs (corticosteroids, nonspecific immunosuppressants such as azathioprine) fail to bring about a marked improvement or cause significant adverse effects. The criteria for determining which targeted therapy to use include:

- the type of autoantibodies (anti-AChR, anti-MuSK...),
- the existence of concomitant diseases (comorbidities),
- the risk of infection,
- patient preferences (infusion or subcutaneous administration, at home or in hospital).

Attarian S. Rev Neurol (Paris). 2024 *Miller-Wilson* et al. *MDA 2025*

Predicting efficacy in order to make better choices

Responses to the same drug differ from one myasthenia gravis patient to the next, even if their "profiles" (severity of the disease, autoantibody type, age...) are similar.

▪ In order to try and determine in advance who will respond best to a particular drug, doctors are trying to identify biological parameters (biomarkers) that are predictive of efficacy. For example, we already know that three variants of the gene that codes for complement component 5 (C5) render eculizumab, a complement C5 inhibitor, ineffective.

Bouwman HB et al. Drug Discov Today. 2024

Good to know

At the Institut de Myologie in France, Rozen Le Panse's team is currently conducting a study on biomarkers that are predictive of therapeutic efficacy in myasthenia gravis.

In Italy, two observational studies are trying to identify biomarkers of a favourable response to complement inhibitors (OPTIMISE study, NCT06455709) and neonatal Fc receptor (FcRn) inhibitors (INFORM study, NCT06685055) in anti-AChR autoantibody positive generalised myasthenia gravis.

*A **biological marker** (or **biomarker** for short) is a measurable characteristic that indicates a normal or pathological biological process. The identification of new biological markers for a disease is very important for monitoring the progression of the disease and the efficacy of new treatments. These markers are physiological (change in blood pressure, heart rate...) or molecular (change in the expression of a protein...).*

Targeting complement

Complement is an immune response mediator which circulates in the blood. It is made up of several proteins. Its components 5 to 9 form a so-called "membrane attack" complex (MAC or C5b-9). During an infection, it works by binding to the surface of cell membranes, creating a pore through which ions and water can enter the cell, which in turn destroys it.

▪ Studies conducted in animal models of myasthenia gravis and human patients have shown that the membrane attack complex is also involved in

myasthenia gravis. Several drug candidates target certain stages of its formation, with the aim of preventing it from forming.
Treatments that target complement are not suitable for myasthenia gravis patients who are positive for anti-MuSK autoantibodies as they belong to the IgG4 subgroup which does not activate complement. This form of myasthenia gravis is, however, responsive to neonatal Fc receptor (FcRn) blockers.

Three marketing authorisations already granted
Zilucoplan (Zilbrysq®), ravulizumab (Ultomiris®) and eculizumab (Soliris®) have been granted marketing authorisation (MA) for anti-AChR autoantibody positive generalised myasthenia gravis in France and in Europe:
- in adults who remain symptomatic, in addition to standard treatment (including immunosuppressants) for zilucoplan (Zilbrysq®) and ravulizumab (Ultomiris®),
- in adults and children from the age of six with refractory forms of myasthenia gravis for eculizumab (Soliris®).

Zilucoplan (Zilbrysq®)

Developed by the pharmaceutical company UCB Pharma, zilucoplan is a is a macrocyclic peptide that inhibits C5. It is self-administered subcutaneously once a day.

Phase III
Efficacy

The authorisations issued by the health authorities were mainly based on the positive results of the phase III RAISE trial.

- Its open-label extension RAISE-XT is still taking place (including in France). The interim results of this trial, which have been shared during several conferences, confirmed the long-term efficacy, safety and tolerability of zilucoplan.

The majority of the participants were "responders" (improvement in MG-ADL and QMG scores) and responder rates continued to increase after the first few months of treatment.
Hewamadduma C et al. MDA 2025 *Howard J et al. MDA 2025*

Phase III
Efficacy

RAISE-XT trial

France and abroad	200 (over 18 years old)	Not recruiting	Dec 2019 – June 2026 3 years of follow-up

NCT04225871

- A French, retrospective (conducted on medical record data), observational study is currently being prepared.

It will evaluate the efficacy (improvement in muscle strength and quality of life), safety and tolerability of zilucoplan over three months.

Efficacy, safety and tolerability over 3 months

France

55 (over 18 years old)

Not yet recruiting

March 2025 – March 2026 3 years of follow-up

NCT06815133

The open-label phase II/III ziMYG trial (NCT06055959) is evaluating Zilbrysq® in adolescents in the United States, South Korea, Poland, Italy and the United Kingdom.

Phase II Dose/effect

Phase III Efficacy

Ravulizumab (Ultomiris®)

Developed by the pharmaceutical company Alexion, a subsidiary of AstraZeneca dedicated to rare diseases, ravulizumab is administered by intravenous infusion, with two weeks between the first and second infusion, then eight weeks between subsequent infusions. Health authorities approved it in myasthenia gravis based on the good results of the phase III CHAMPION MG trial and its extension.

Aguirre F et al. J Comp Eff Res. 2024

Phase III Efficacy

- Ravulizumab continues to be evaluated in adults and children (including in France).

Paediatric trial

France and abroad

12 (6 to 17 years old)

Recruiting

June 2023 - July 2028 4 months of follow-up

NCT05644561

Phase III Efficacy

An observational study of the safety of using a complement C5 inhibitor during pregnancy and/or breastfeeding is currently taking place in the United States (NCT06312644).

Eculizumab (Soliris®)

Eculizumab (Soliris®), which is also being developed by Alexion, is administered by intravenous infusion once a week for one month, then once every two weeks.

- During the past year, positive results have been published for eculizumab in anti-AChR autoantibody positive generalised myasthenia gravis in "real life" in adults from the retrospective study ELEVATE, as well as in adolescents (phase III trial NCT03759366).

Habib AA et al. J Neurol. 2024 *Brandsema JF et al. Pediatr Neurol. 2024*

Phase III Efficacy

The C5ITs registry (NCT04202341) of people with myasthenia gravis who have received eculizumab or ravulizumab is currently being set up in the United States, Canada, Germany and Italy in order to better understand the long-term effects and safety of these drugs.

Cemdisiran (ALN-CC5) and pozelimab (Veopoz®)

Cemdisiran is a small interfering RNA (siRNA) molecule that targets complement component 5. Pozelimab is a monoclonal antibody which is also directed against C5. In August 2023, the American health authorities granted it its first marketing authorisation for a genetic immune disease called CHAPLE disease. Both are administered subcutaneously.

A small interfering RNA (**siRNA**) molecule binds specifically to a messenger RNA (mRNA) molecule, to which it is complementary. In doing so, it prevents the expression of the corresponding genes into proteins.

▪ Both products were developed by the pharmaceutical company Regeneron, which is conducting an international trial to explore the efficacy and safety of the pozelimab - cemdisiran combination vs cemdisiran monotherapy or placebo in anti-AChR or anti-LRP4 autoantibody positive myasthenia gravis.

Phase III
Efficacy

NIMBLE trial

France and abroad	335 (over 18 years old)	Recruiting	Dec 2021 – March 2029 3 years of follow-up

NCT05070858

Gefurulimab (ALXN1720)

Gefurulimab, developed by Alexion, is an antibody directed against C5 which is injected subcutaneously once a week. A placebo-controlled clinical trial is currently being conducted (including in France) in anti-AChR autoantibody positive generalised myasthenia gravis. An open-label trial will follow.

Phase III
Efficacy

Placebo-controlled trial

France and abroad	260 (over 18 years old)	Not recruiting	Nov 2022 - July 2027 6 months of follow-up

NCT05556096

➔ An open-label trial (NCT06607627) is evaluating gefurulimab in anti-AChR autoantibody positive generalised myasthenia gravis in children and adolescents in Taiwan, Poland, Brazil and the United States.

Dianthus Therapeutics is developing **DNTH103**, a monoclonal antibody that targets complement component 1 (C1) which is administered subcutaneously every two weeks.

▪ The international MAGIC trial is evaluating DNTH103 vs placebo over three months (then in a one-year open-label extension) in adults with anti-AChR autoantibody positive generalised myasthenia gravis. The initial results are expected to be published in the second half of 2025.
Dianthus Therapeutics. Press release 11 March 2025

Placebo-controlled MAGIC trial

Phase II
Dose/effect

France and abroad	60 (18 to 75 years old)	Recruiting	Feb 2024 – Dec 2027 9 months of follow-up

NCT06282159

Iptacopan (Fabhalta®)

NEW

Iptacopan from Novartis is already approved in France (capsule form) for the treatment of another disease called paroxysmal nocturnal haemoglobinuria. It is a factor B inhibitor.

In 10 countries around the world (but not in France), a phase III trial is evaluating iptacopan, first vs placebo then in an open-label extension, in anti-AChR autoantibody positive generalised myasthenia gravis that is refractory to nonspecific immunosuppressants (NCT06517758). It is aiming to recruit 146 participants between the ages of 18 75 years old.

Phase III
Efficacy

*A **placebo** is a product whose appearance is identical to a particular medicine but does not contain any active substances. In a clinical trial, a placebo is used to measure the true action of a medicine by comparing the effects of the medicine (which contains the active substance) to those of the placebo.*

Blocking neonatal Fc receptors

Essential receptors for autoantibodies

Immunoglobulin G (IgG) is the main type of antibody produced by the immune system. Neonatal Fc receptors (FcRns) bind to IgG antibodies, preventing them from being degraded. In doing so, they help extend the time that IgG antibodies circulate in the blood, and therefore prolong immunity. The autoantibodies produced in myasthenia gravis are also IgG antibodies. FcRns therefore contribute to prolonging their autoimmune action.

Certain drugs specifically target FcRns. They consist of antibodies or antibody fragments directed against these receptors. By blocking FcRns, they bring about a reduction in all circulating IgG antibodies and, including autoantibodies.

Two marketing authorisations already granted

Efgartigimod (Vyvgart®) and rozanolixizumab (Rystiggo®) were granted marketing authorisation (MA) in Europe, then in France.

They are indicated in addition to "standard treatment" in adults with symptomatic generalised myasthenia gravis with anti-AChR autoantibodies for efgartigimod, and anti-AChR or anti-MuSK autoantibodies for rozanolixizumab.

Efgartigimod (Vyvgart®)

Developed by the pharmaceutical company argenx, efgartigimod is administered via intravenous infusion or subcutaneous injection by the patient or a caregiver after receiving training in cycles of one infusion/injection per week for four weeks, in accordance with the progression of the disease.

- Several papers this year have confirmed its rapid onset of action, long-term efficacy, and the noninferiority of its subcutaneous form to its intravenous form.

Howard JF Jr et al. Neurotherapeutics. 2024 *Luo S et al. Ann Clin Transl Neurol. 2024*
Dewilde S et al. J Neurol Sci. 2024 *Teranishi H et al. Expert Opin Biol Ther. 2025*

- Several different teams have also published results on the efficacy and rapid onset of action of efgartigimod in other indications, such as myasthenic crisis and seronegative myasthenia gravis.

Song J et al. Front Immunol. 2024
Antozzi C et al. Neurol Sci. 2025
Shi F et al. BMC Neurol. 2025
Zhou Y et al. Ther Adv Neurol Disord. 2025

Efgartigimod is being evaluated in around 10 trials currently underway or in preparation around the world for different indications (ocular myasthenia gravis, myasthenic crisis, immunoglobulin dependence, in the days before and after a thymectomy, during pregnancy...). France is participating in four of these trials.

*An **open-label trial** is a clinical trial in which the doctors and participants know what treatment is being administered.*

- The first two are open-label trials evaluating efgartigimod administered intravenously (ADAPT Jr) or subcutaneously (ADAPT Jr SC) in children and adolescents with anti-AChR autoantibody positive generalised myasthenia gravis.

Phase II
Dose/effect

Phase III
Efficacy

ADAPT Jr trial

France and abroad	12 (2 to 18 years old)	Recruiting	Oct 2021 – March 2027 6.5 months of follow-up

NCT04833894

Phase II
Dose/effect

Phase III
Efficacy

ADAPT Jr SC trial

France and abroad	12 (2 to 17 years old)	Recruiting	June 2024 – Sept 2026 3 months of follow-up

NCT06392386

- The ADAPT SERON is recruiting adults with anti-AChR autoantibody seronegative generalised myasthenia gravis. It is evaluating efgartigimod vs placebo and will be followed by an open-label extension.

Phase III
Efficacy

ADAPT SERON trial

France and abroad	110 (over 18 years old)	Recruiting	April 2024 – July 2027 7 months of follow-up

NCT06298552

- Recruitment for the fourth trial (ADAPT NXT, NCT04980495) has been completed. It is an open-label trial that is due to be completed in April 2026. It is comparing two dosing regimens in adults with anti-AChR autoantibody positive generalised myasthenia gravis.

Rozanolixizumab (Rystiggo®)

Developed by the pharmaceutical company UCB Pharma, rozanolixizumab is administered subcutaneously once weekly for six weeks, with subsequent six-week cycles to be administered according to the course of the disease. It was made eligible for reimbursement from health insurers in France in March 2025.

Decree dated 14 March 2025, JORF (Journal officiel de la République française [Official Journal of the French Republic]) no. 0067 dated 19 March 2025 [page in French]

Phase III
Efficacy

▪ Further results from the phase III MycarinG trial and its open-label extension (which France participated in) released in the last few months demonstrated or confirmed the efficacy of rozanolixizumab on physical fatigue, muscle weakness and ocular symptoms in participants with anti-MuSK autoantibody positive myasthenia gravis, the durable nature of its benefits and that it was well tolerated.

Habib AA et al. Ther Adv Neurol Disord. 2024 *Habib AA et al. Neurology. 2024*
Bril V et al. MDA 2025 *Habib AA et al. MDA 2025*
Bril V et al. Neuromuscul Dis. 2025 *Habib AA et al. J Neuromuscul Dis. 2025*
Bril V et al. J Neurol. 2025

The open-label rozanolixizumab trial called roMyG is recruiting children and adolescents with moderate to severe anti-AChR or anti-MuSK autoantibody positive myasthenia gravis in the United States, Italy, Poland and Taiwan.

Nipocalimab (or M281)

Developed by the pharmaceutical company Janssen, nipocalimab has orphan drug designation in Europe for an autoimmune blood disorder. It is administered by intravenous infusion every two weeks.

Phase II
Dose/effect

▪ The phase II VIVACITY-MG trial showed that this drug candidate induces a rapid and significant decrease in IgG antibody levels, but no significant differences in terms of the impact of the manifestations of the disease on day-to-day activities (MG-ADL score).

The results of the VIVACITY-MG3 trial

The phase III, placebo-controlled VIVACITY-MG3 trial evaluated nipocalimab administered for nearly six months in 196 adults with refractory generalised myasthenia gravis, 153 of whom were positive for anti-AChR, anti-MuSK or anti-LRP4 autoantibodies.

▪ The improvement in MG-ADL scores was greater in the nipocalimab group than in the placebo group (-4.70 vs -3.25) at the end of the trial, with a significant average difference from the first week. A significant improvement in QMG scores was also reported.

▪ Adverse events were equally common in both groups (84% of the participants) and included infections (43%) and headaches (14% vs 17%).

Antozzi C et al. Lancet Neurol. 2025 *Ait-Tihyaty M et al. MDA 2025.*

▪ The open-label extension phase of the VIVACITY-MG3 trial will provide long-term efficacy, safety and tolerability data.

Phase III
Efficacy

Open-label extension of the VIVACITY-MG3 trial

France and abroad	196 (over 18 years old)	Recruiting	Ending in April 2026 4 years of follow-up

NCT04951622

▪ The phase II/III VIBRANCE-MG trial (NCT05265273), conducted in seven adolescents with refractory anti-AChR autoantibody positive generalised myasthenia gravis treated for 5.5 months with nipocalimab, demonstrated the efficacy of the drug candidate (decrease in IgG antibody levels, improved MG-ADL and QMG scores) and that it was well tolerated.

Strober J et al. MDA 2025

Targeting T cells and B cells using upstream therapies

Inebilizumab (Uplizna®)

Manufactured by the pharmaceutical company Amgen and currently indicated for the treatment of a form of neuromyelitis optica spectrum disorder, inebilizumab is a monoclonal antibody that targets **CD19,** a protein found on the surface of B cells. B cells become plasma cells which produce autoantibodies.

▪ Inebilizumab is administered as an intravenous infusion twice a year following an initial "loading dose". The American health authorities granted it orphan drug designation for myasthenia gravis in January 2025.

*The **"orphan drug"** designation is applied to drug candidates (whose efficacy has not yet been demonstrated) in rare diseases, with the aim of facilitating the various stages of their development.*

Initial phase III results

The MINT trial is evaluating Uplizna® vs placebo in anti-AChR (190 participants) and anti-MuSK (48 participants) autoantibody positive generalised myasthenia gravis in around 20 countries, including France. It will be followed by an open-label extension. Published in April 2025, the results of the first part of the trail (placebo-controlled) showed that:

▪ inebilizumab achieved the primary endpoint chosen for this trial - a significant improvement in MG-ADL scores was observed in the inebilizumab group (-4.2) compared to the placebo group (-2.2) at week 26;

▪ this efficacy was durable with, for the anti-AChR autoantibody positive patients monitored for 52 weeks, reductions in MG-ADL scores of at least three points in 72.3% of cases vs 45.2% in the placebo group;

▪ QMG scores saw similar improvements,

▪ at week 26, side effects had been experienced by 80.7% of the participants on inebilizumab and 73.1% of those on placebo, the most common ones being infusion-related reactions, cough, headaches, nasopharyngitis and urinary tract infections.

Nowak R et al. N Engl. J. Med. 2025 *Nowak R et al. MDA 2025*

▪ The trial will continue for another two years with an open-label period.

Phase III
Efficacy

MINT trial

France and abroad	238 (over 18 years old)	Not recruiting	August 2020 – Nov 2027 4 years of follow-up

NCT04524273

Blinatumomab (Blincyto®)

NEW

Blinatumomab was created by the pharmaceutical company Amgen to treat a blood cancer which develops from B cells. It has two targets: **CD19** (expressed by B cells) **CD3** (found on the surface of T cells).

Phase II
Dose/effect

Phase III
Efficacy

In China, two phase II/III open-label trials (NCT06684184, NCT06836973) are currently in preparation. Sponsored by two doctors, they will measure the effects, safety and tolerability of blinatumomab in a total of 12 adults with anti-AChR, anti-MuSK or anti-LRP4 autoantibody positive refractory myasthenia gravis.

Rituximab (MabThera®, Truxima®)

Rituximab is a monoclonal antibody that binds specifically to **CD20**, a protein which is found only on the surface of B cells. This binding induces the destruction of these B cells, with the aim of reducing

autoantibody production. Rituximab has already been approved for use in rheumatoid arthritis (another autoimmune disease) and certain blood cancers.

▪ This drug is often prescribed in myasthenia gravis after the usual treatments (cholinesterase inhibitors, corticosteroids...) have failed. In order to determine whether it could be prescribed earlier, a team from CHU de Nice [Nice University Hospital] analysed the medical records of 68 people with generalised myasthenia gravis, half of whom had a severe form of the disease.

Forty-nine of these patients were treated with rituximab alone at the start of their disease, while 19 received rituximab combined with corticosteroids as the disease was more severe initially. Levels of muscle fatigability were equally low in both group three months after starting rituximab, meaning that it is as effective alone as when combined with corticosteroids.
Héraud C et al. J Neurol. 2024

▪ The Fondation Ophtalmologique Adolphe de Rothschild [Adolphe de Rothschild Ophthalmology Foundation] in Paris is preparing a trial in recent (diagnosed within the last six months) ocular myasthenia gravis which has not been previously treated with immunosuppressants. It is aiming to determine whether corticosteroids combined with rituximab in the event of recurrence of ocular symptoms when reducing corticosteroid doses prevents generalisation of the disease.

***Corticosteroids** are hormones secreted by the adrenal glands and are essential for the body's survival.*
Synthetic corticosteroids are used as medications, mainly to reduce inflammatory, allergic and immune reactions (anti-inflammatories, antiallergics and immunosuppressants). Because they also act on other bodily functions, they have several possible side effects. Taking corticosteroids should never be stopped abruptly and always requires strict medical supervision.

IMCOMG trial in ocular myasthenia gravis

Phase III
Efficacy

France | **128 (over 18 years old)** | **Not yet recruiting** | **June 2024 – June 2029 2 years of follow-up**

NCT06342544

In Italy, the phase III REFINE trial (NCT05868837) is evaluating rituximab vs placebo in 40 adults with anti-AChR or anti-MuSK autoantibody positive myasthenia gravis. It is due to be completed in July 2025.

B007

NEW

Developed by Shanghai Jiaolian Drug Development, B007 is also an **anti-CD20** monoclonal antibody. It is being developed in several different autoimmune diseases.

A phase II/III placebo-controlled trial (NCT06447597) in China is currently recruiting 104 adults with anti-AChR or anti-MuSK autoantibody positive generalised myasthenia gravis.

Remibrutinib (LOU064)

NEW

Remibrutinib, developed by Novartis, specifically inhibits **Bruton tyrosine kinase** (BTK), a protein which plays an essential role in the development of B cells from their precursor cells. Administered in tablet form, remibrutinib is currently undergoing trials for chronic urticaria, hidradenitis suppurativa and multiple sclerosis.

The RELIEVE trial (NCT06744920) was launched this year in the United States in adults with anti-AChR or anti-MuSK autoantibody positive

Phase III
Efficacy

generalised myasthenia gravis. It includes an initial placebo-controlled part (six months) followed by an open-label extension (up to five years) and is aiming to recruit 180 participants.

Telitacicept (or RC18)

Created by the pharmaceutical company RemeGen, telitacicept is being developed in several autoimmune diseases, including myasthenia gravis. It has been granted marketing authorisation for lupus in China, and was granted orphan drug designation for myasthenia gravis by the North American health authorities in 2022.

*The **"orphan drug"** designation is applied to drug candidates (whose efficacy has not yet been demonstrated) in rare diseases, with the aim of facilitating the various stages of their development.*

▪ It is a biological therapy (recombinant fusion protein) that binds to **BLyS and APRIL**, two proteins which promote the development and survival of B cells (which produce autoantibodies). Telitacicept limits this development and survival. It is administered subcutaneously on a weekly basis.

Phase II
Dose/effect

Phase II results

Telitacicept was evaluated as part of an open-label trial (NCT04302103) conducted in 29 adults with anti-AChR or anti-MuSK autoantibody positive myasthenia gravis in China. The participants were randomised to receive either 160 or 240 mg of telitacicept subcutaneously once a week for 24 weeks. The results, published in August 2024, showed:

▪ average reductions in QMG scores of 5.8 and 9.5 points in the 160 and 240 mg groups, respectively, after 12 weeks of treatment;

▪ average reductions in QMG scores of 7.7 and 9.6 points, respectively, after 5.5 months of treatment,

▪ reduced levels of immunoglobulin A, G and M in the blood.

Yin J et al. Eur J Neurol. 2024

Phase III
Efficacy

RemeGen is conducting two phase III trials (NCT05737160 and NCT06456580) to evaluate telitacicept vs placebo in anti-AChR and anti-MuSK autoantibody positive generalised myasthenia gravis. They are aiming to recruit a total of 280 participants in China, the United States and Poland.

Phase IV
Pharmacovigilance

Two trials (NCT06723548 and NCT06827587) currently in preparation will test telitacicept combined with low-dose corticosteroids or efgartigimod (Vyvgart®) in around 100 adults with anti-AChR autoantibody positive generalised myasthenia gravis. The participating countries and investigator sites are not yet known.

Cladribine (Mavenclad®)

NEW

Oral cladribine (Mavenclad®), developed by the pharmaceutical company Merck, has been indicated for the treatment of very active forms of multiple sclerosis (another autoimmune disease) since 2021.

Cladribine is a nucleoside analogue that was initially developed to treat a type of blood cancer. Once administered, it transforms into a compound that replaces natural nucleosides (structural components of DNA). Cladribine therefore inhibits DNA synthesis and repair in B cells and T cells, causing them to be destroyed.

The results of an open-label pilot study
In Poland, 13 people with a refractory form of myasthenia gravis received several cycles of cladribine, in accordance with the course of their disease. Eleven of them saw a significant improvement in their Myasthenia Gravis Composite scores, going from 15.1 to 6.3 within four months of starting treatment, enabling a five-fold reduction in their corticosteroid doses. None of the patients required additional treatment (immunoglobulins or plasmapheresis) and cladribine was well tolerated.
Rejdak K et al. Eur J Neurol. 2020

Phase III
Efficacy

Since August 2024, the MyClad trial (NCT06463587) has been evaluating the efficacy, safety and tolerability of an oral form of cladribine in 240 adults with seronegative or seropositive (anti-AChR, anti-MuSK or anti-LRP4 autoantibody positive) refractory myasthenia gravis in nine countries around the world. The first participant was treated in August 2024.
Merck. Press release 29 August 2024.

For several neuromuscular diseases

NMD670

NEW

NMD670 is an orally-administered (tablets) small molecule developed by NMD Pharma. It inhibits the skeletal muscle-specific **ClC-1 chloride channel** which is involved in regulating the transmission of electrical signals at the neuromuscular junction and the excitability of muscle fibres during intense exercise.

It is being evaluated in myasthenia gravis, Charcot-Marie-Tooth disease and spinal muscular atrophy (SMA).

Phase II
Dose/effect

Preclinical and phase II results
NMD670 alone or in combination with an FcRn blocker improved the transmission of electrical signals at the neuromuscular junction and muscle function in rat models of myasthenia gravis. After encouraging results were obtained from a phase I trial conducted in health volunteers, a second trial was carried out in 12 myasthenia gravis patients. The well-tolerated drug candidate bought about significant improvements in QMG scores.
Skov M et al. Sci Transl Med. 2024 *Huus N et al. MDA 2025*
Ruijs TQ et al. Clin Pharmacol Ther. 2025

▪ The placebo-controlled SYNAPSE-MG trial is evaluating NMD670 administered twice a day for 21 days. It is recruiting adults with anti-AChR or anti-MuSK autoantibody positive generalised myasthenia gravis, including in France.

Phase II
Dose/effect

Placebo-controlled SYNAPSE-MG trial

France and abroad	84 (over 18 years old)	Recruiting	May 2024 – Nov 2025 28 days of follow-up

NCT06414954

What's new with "classic" treatments?

Older treatments for myasthenia gravis continue to be studied and feature in clinical trials with the aim of refining their use (indications, route of administration, safety and tolerability...).

Better management of treatment with TPE

Therapeutic patient education (TPE) enables people with a chronic disease to acquire or maintain useful skills to help better manage their everyday lives. Its aim is to help them to better understand their disease (or a relative or friend's disease) and its treatments, as well as how to live with it and manage it more effectively, therefore improving the disease's care and course. University hospitals in Grenoble, Toulouse, Marseille and Strasbourg offer myasthenia gravis-specific TPE programmes.

FILNEMUS TPE [page in French]

Cholinesterase inhibitors

Prescribed the most

According to the French STAMINA study conducted on data from the Système National des Données de Santé [French National Health Data System], cholinesterase inhibitors (Mestinon®, Mytelase®) taken alone are the most common treatment for myasthenia gravis in France (half of patients treated), ahead of immunosuppressants with or without corticosteroids.

Did you know?

A not-so-rare disease

The STAMINA study had already revealed that myasthenia gravis was more common than originally estimated, affecting nearly 23,000 adults in France, a third of whom are over 65 years old. Approximately one person in every 3,000 has myasthenia gravis in France, with around 1,500 new cases every year.

▪ The STAMINA study also confirmed the great variability of symptoms in myasthenia gravis, not only from person to person, but also in the same person over the course of their life, requiring treatment to be modified. Adults with myasthenia gravis in France diagnosed in 2012 or 2013 changed treatment category on average nearly three times in six years. This highlights the importance of regular monitoring and adapting prescriptions over time if needed.

Tard C et al. J Neurol. 2024

Often a bad combo with anti-MuSK autoantibody positive myasthenia gravis

In recent years, various papers have reported that cholinesterase inhibitors may be poorly tolerated, are not always effective and may even be harmful in anti-MuSK autoantibody positive myasthenia gravis.

▪ The results of an Italian study conducted on data from 202 patients confirmed this. The vast majority of these patients (82%) were treated with cholinesterase inhibitors during their first consultation at a specialist centre, but only 4% of them reported experiencing a benefit from them. A third experienced a worsening of muscle weakness, and nearly 77% reported at least one side effect of the treatment.

Ricciardi R et al. J Neurol Sci. 2024

Gastrointestinal side effects in the crosshairs

DAS-001 is a drug developed by DAS Therapeutics that combines a cholinesterase inhibitor (pyridostigmine, Mestinon®) with ondansetron, a drug that has already been approved for the prevention and treatment of nausea and vomiting induced by chemotherapy or radiotherapy.

Phase II
Dose/effect

➔ In the United States, a phase II trial (NCT04226170) is currently recruiting 24 adults with anti-AChR autoantibody positive myasthenia gravis. They will receive either pyridostigmine combined with a placebo, or DAS-001 for six weeks.

Immunoglobulins vs placebo

At the end of 2024, the results of an international trial (NCT02473952) that France participated in were published. The trial evaluated intravenous immunoglobulin therapy (IVIg) in 62 participants with anti-AChR autoantibody positive myasthenia gravis. The participants received "standard of care" treatment (cholinesterase inhibitors and/or corticosteroids and/or nonspecific immunosuppressants) at a stable dose as well as IVIg every three weeks, or a placebo.

▪ The investigators recorded statistically insignificant differences in efficacy between the IVIg and placebo groups 5.5 months after starting the treatment.

Bril V et al. Muscle Nerve. 2025

Repurposing Firdapse®

Sold under the name Firdapse® by Catalyst Pharmaceuticals, amifampridine phosphate (or 3,4-diaminopyridine, or even 3,4-DAP) facilitates the release of acetylcholine into the synaptic cleft.

Firdapse® is indicated as a symptomatic treatment for Lambert-Eaton myasthenic syndrome in adults and certain congenital myasthenic syndromes (other neuromuscular diseases which involve neuromuscular junction dysfunction).
It could be an additional treatment option in myasthenia gravis, for example, when conventional treatments are not able to sufficiently control disease manifestations or in cases of poor tolerance to cholinesterase inhibitors.

➔ Since 2023, a university hospital in the Netherlands has been conducting a placebo-controlled trial called IMPACT-MG (NCT05919407) which is evaluating amifampridine and pyridostigmine in 24 adults with anti-AChR autoantibody positive generalised or ocular myasthenia gravis.

Drug repurposing *consists of using a drug for a condition that is different from what it was initially indicated for.*

Congenital myasthenic syndromes *are caused by abnormalities in the genes that code for neuromuscular junction components (acetylcholinesterase, acetylcholine receptors). Unlike myasthenia gravis, congenital myasthenic syndromes are genetic conditions.*

Phase III
Efficacy

Traditional Chinese medicine

Buzhong Yiqi decoction contains a combination of various different plants. It is used in traditional Chinese medicine to treat myasthenia gravis.

▪ It has been shown to be effective on the manifestations of the disease in mice, reducing inflammation, improving mitochondrial function and regulating the JAK2/STAT3/AKT signalling pathway involved in inflammation and immunity.

Zeng Y et al. Allergol Immunopathol (Madr). 2024

A hospital in Taiwan is recruiting 112 people over the age of 20 who have the ocular form of myasthenia gravis with the aim of evaluating the efficacy of combining Buzhong Yiqi decoction with Mestinon® vs placebo (NCT06881173).

Thymectomy

A very favourable benefit-risk ratio

Phase III
Efficacy

Thymectomy (a surgery that consists of removing the thymus) has been used for decades to treat myasthenia gravis with thymoma. In 2016, a phase III, international trial called MGTX showed that thymectomy is also beneficial in non-thymomatous anti-AChR autoantibody positive myasthenia gravis.

- A retrospective study published in 2023 (which however contained several biases) raised the issue of an increased long-term risk of autoimmune diseases, cancer and mortality after thymectomy.

In response, international experts in myasthenia gravis and cardiothoracic surgery reviewed current data on the thymus.
They concluded that for patients with anti-AChR autoantibody positive myasthenia gravis and those diagnosed with thymoma, thymectomy has significant benefits that far outweigh the potential risks raised by the retrospective study.
A team of Israeli doctors arrived at the same conclusion after analysing data from 456 myasthenia gravis patients with or without thymectomy.
Kaminski HJ et al. Neurology. 2024 *Tsirkin I et al. Front Immunol. 2025*

In older adults too

In patients **with thymoma**, thymectomy leads to a significant improvement in myasthenia gravis in 88% of cases according to an Italian study conducted on follow-up data from 66 patients over the age of 65. Six percent of them achieved complete stable remission (no signs or symptoms of the disease, with no treatment), nearly 17% experienced pharmacological remission (with treatment) and 65% achieved "minimal manifestation status" (weakness in some muscles on examination).
Lococo F et al. Updates Surg. 2024

- And in patients **without thymoma**? An analysis of 20 studies showed that when myasthenia gravis started after the age of 40, the effects of thymectomy were superior to those of medication alone, but the difference between the two was not significant. However, it was significant in the group of patients whose disease started at the age of 45 or older, and those who underwent thymectomy at the age of 50 or older.

Across all of the studies, improvements were seen in 24% to 44% of the patients following thymectomy, with the highest rates observed when the procedure was performed less than three years after myasthenia gravis was diagnosed.
Chen J et al. Eur J Neurol. 2025

Exercise

Tailored exercise programmes are recommended once the disease has stabilised. They help combat the deconditioning caused by myasthenia gravis, but also the side effects of long-term corticosteroid use (if applicable).

- In the United States, the MG-Ex trial (NCT06491238) is evaluating the feasibility, acceptability and tolerability of two three-month-long exercise programmes of different intensities.
- In the Netherlands, the FIT to ACT-MG study (NCT06659627) is comparing the effects of four months of tailored exercise (a programme consisting of three sessions a week on an exercise bike) or cognitive behavioural therapy on fatigue.
- In Sweden, the DIG-MG trial (NCT05992025) evaluated how a 12-week online coaching programme on exercise and sleep affected fatigue, with participant follow-up carried out via a "smart" ring (Oura Ring) capable of measuring various parameters. The data is currently being analysed.

Databases and observational studies

Healthcare databases, registries and data warehouses, and observational studies are essential for understanding the natural history of a disease, monitoring its prevalence, and improving its diagnosis and treatment.

*The so-called **natural history** of a disease, as doctors refer to it, is the description of different manifestations of a disease and their progression over time without treatment.*

For patients in France

The database created by Sonia Berrih-Aknin (Institut de Myologie, Paris) with the support of AFM-Téléthon was not designed to be exhaustive but to aid research projects which advance our understanding of myasthenia gravis.

*A **muscle biopsy** is a procedure which involves removing a small fragment of muscle tissue under local anaesthetic. The fragments of muscle tissue are then studied under a microscope. The different methods used to prepare the tissue enables abnormalities in the morphology and/or structure of the muscle fibres to be detected and/or deficiencies in certain proteins to be identified.*
➤➤ Diagnostic des maladies neuromusculaires [Diagnosis of neuromuscular diseases], Savoir & Comprendre references documents, AFM-Téléthon.

- It collects information (symptoms, blood test results, muscle biopsy analyses, thymus analyses...) on around 50 new patients every year who have myasthenia gravis, with or without thymoma.

French database

France

2,162 patients

Recruiting

Created in 1986

A new French registry in the pipeline
FILNEMUS (a French healthcare network for rare neuromuscular diseases) is preparing to launch a healthcare data warehouse called BASE MG, hosted by the Banque Nationale de Données Maladies Rares [French National Registry of Rare Diseases]. It will collect data from adults being monitored for myasthenia gravis in specialist centres in France with the aim of registering 1,000 new participants every year for five years.

For patients outside France

Various registries and databases compile data from myasthenia gravis patients in different countries around the world.

Their objective is often **general,** such as improving our understanding of the disease and its treatment. This is the case for the Explore MG registry (NCT03792659), the Explore-MG2 registry (NCT06002945), the Myasthenia gravis patient registry (MGR) and the Duke myasthenia gravis clinic registry in the United States, as well as the Myasthenia Gravis Registry of China (NCT06241521) created last year in Shanghai.

Other registries focus on a **specific** topic, such as the study of myasthenic crisis (NCT04837625) or anti-MuSK autoantibody positive myasthenia gravis (NCT06259071).

Observational studies

In France

The Institut de Myologie (Paris) is preparing to launch the MyaRESP study. Its aim is to describe the characteristics of the breathlessness (dyspnoea) experienced during day-to-day activities by some myasthenia gravis patients, and to better understand the factors that contribute to this breathlessness and which tests are the best at identifying them.

▪ The participants (over 18 years old) will undergo several tests including lung function tests, a sleep study, a stress test and a six-minute walk test.

MyaRESP observational study

France

50
(over 18 years old)

Not yet recruiting

May 2025 – June 2028
1 day of follow-up

NCT06866652

▪ CHU de Clermont-Ferrand [Clermont-Ferrand University Hospital] is studying the prevalence and impact of fatigue in adult patients who had a consultation for their myasthenia gravis between January 2022 and December 2024. The patients are required to fill in various questionnaires.

My Asthenia observational study

France

100
(over 18 years old)

Recruiting

Jan 2025 – Oct 2025
6 months of follow-up

NCT06877403

Outside France

Several observational studies in myasthenia gravis are being conducted outside France.

➔ In the Netherlands and Germany, the CAPTURE–MG (NCT06743490) and POWER-MG studies (NCT06441825) are using wearable devices to monitor the symptoms and activity of the disease in real life.

➔ In Italy, the MYCOG study (NCT06718855) is attempting to define the prevalence of cognitive difficulties in 150 adults with myasthenia gravis according to autoantibody type and treatment taken. It is also aiming to evaluate the impact of cognitive impairment on work and day-to-day activities, mental health (anxiety, depression) and quality of life.

***Cognitive functions** are the mental processes that enable us to acquire and use knowledge (perception, attention, memory, information processing, language, problem solving, decision making, ...).*

New developments in the disease, diagnosis and monitoring

A better understanding of the risk factors

What causes the immune system dysfunction in myasthenia gravis?
Like in most autoimmune diseases, the immune system dysfunction that occurs in myasthenia gravis is thought to be caused by a combination of several factors.
- A genetic predisposition. Myasthenia gravis occurs in people who have a genetic susceptibility to developing an autoimmune disease (myasthenia gravis or another disease). This susceptibility is polygenic (influenced by several genes) and is passed down to children, but is not enough to cause an autoimmune disease.
- Individual "endogenous" and "exogenous" factors and events (such as hormones for the former, and medication, infections... for the latter).

*A **gene** is a "segment" of DNA located in a very specific position (locus) on a chromosome. Each gene contains information that constitutes the "manufacturing plan" for a protein.*

The genetics become clearer

An international team analysed genetic and clinical data from nearly 10,000 myasthenia gravis patients compared to hundreds of thousands of controls, making it the largest study of this kind to be conducted in this disease to date. They concluded that:

- certain variants in different DNA regions are strongly linked to myasthenia gravis, two of them appearing to be associated with the early-onset form (manifestations before the age of 50) and four of them with the late-onset form;
- particular alleles of the genes in the major histocompatibility complex (HLA), which enables the immune system to recognise the body's cells, seem to modulate the time of disease onset;
- a polygenic risk score specific to myasthenia gravis makes it possible to predict the disease and could, in the long term, be integrated into the assessment carried out to make the diagnosis.

Braun A et al. Nat Commun. 2024

Drugs and the environment

Good to know
In contrast to the genome, the exposome is defined as all of the non-genetic factors an organism is exposed to in its lifetime (pollutants, foods, microorganisms, stress factors, drugs...).
- These factors may be involved in the onset of autoimmune diseases via "epigenetic" mechanisms, that is, by causing changes in gene expression without modifying the genes themselves (no genetic mutations).
- Progress in this area would enable us to have a better understanding of how autoimmune diseases start, and improve their diagnosis (by identifying epigenetic "signatures") and treatment.

Danieli MG et al. Autoimmun Rev. 2024

- **Statins** are drugs commonly prescribed to help lower levels of bad cholesterol. Previous publications have warned that they may cause myasthenia gravis or worsen it.

A new study conducted using population-based medical records in Hong Kong confirmed this risk. The risk only seemed to be present during the first seven months of treatment, and was at its maximum during the first month.

Xu W et al. Nat Commun. 2024

▪ A 43-year-old women experienced two myasthenic crises three months apart which required her to be hospitalised in intensive care. Two weeks before these events, she had **dyed her hair** red, then blue.
The dyes used both contained methylisothiazolinone, a product used to replace parabens which had not previously been identified as a trigger for myasthenic crises.
Gomez Rosado JO et al. Cureus. 2024

▪ In a study conducted in Italy in 316 myasthenia gravis patients, the number of new cases was highest **in the summer**, particularly during periods when outdoor temperatures were at their highest.
Heat actually impairs neuromuscular junction functionality. Common viral infections during the summer and antibiotics may also play a role in worsening the symptoms of the disease, making it more "obvious".
Falso S et al. J Neuroimmunol. 2025

▪ So what could the consequences of **global warming** be? To try to predict this, a team of researchers studied the medical records of myasthenia gravis patients from 10 US states.
The 85,008 patients identified in these states in the second period (2020 - 2022) had higher rates of disease exacerbation and mortality than the 5,538 patients identified in the same states in the first period (2007 - 2009). And these differences were more marked in the five states that recorded the greatest temperature increases between the two periods (+ 0.86 °C ± 0.13 °C).
Jaffry K et al; Neurology 2024

Female hormones at puberty and the thymus

A team from the Institut de Myologie used a French research database to compare the medical records of nearly 1,000 prepubescent, postpubescent and adult myasthenia gravis patients.
▪ Their analysis showed that there seems to be a turning point at puberty in young girls. When the disease occurred earlier (prepubescent form), thymectomy was less common (32.5% vs 42.5% in other forms) and the time between diagnosis and thymectomy was twice as long.
The frequency of thymic hyperplasia (95% of cases) and the number of germinal centres were highest in women and girls, particularly in those whose disease occurred after puberty. These results support the existence of a link between female sex hormones and modulation of thymus function.
Truffault F et al. Sci Rep. 2024

Improving diagnosis remains relevant

From ocular to generalised myasthenia gravis

Myasthenia gravis sometimes starts with isolated ocular manifestations (double vision, drooping of the upper eyelids...).
In these cases, the onset of the disease tends to be later and time to diagnosis longer, but the treatment required is less intense and takes less time to control symptoms than when the disease is generalised from the outset.
▪ The results of a study conducted in 350 Danish patients did not reveal any other major differences between ocular and generalised myasthenia gravis, two forms of the same disease of increasing severity. Levels of anti-AChR

autoantibodies in the blood over 100 nmol/L seem to be predicative of the generalisation of ocular forms.
Axelsen KH et al. Neuromuscul Disord. 2024

The impact of delayed diagnosis

In a study carried out on nearly 400 myasthenia gravis patients from five European countries (France, Germany, Italy, Spain and the United Kingdom), a diagnosis of myasthenia gravis was made on average 363 days after the first manifestations of the disease.

- This diagnosis took over a year for 27% of the patients, and in this group the disease was more severe, symptoms such as fatigue, anxiety and depression more common, and quality of life poorer more often than in the group of patients who were diagnosed quicker (in one year or less).

Cortés-Vicente E et al. Ann Clin Transl Neurol. 2024

A tool for improving the diagnosis of seronegative myasthenia gravis

Between 10 and 15% of myasthenia gravis patients have no detectable autoantibodies in their blood. This is referred to as seronegative myasthenia gravis, a scenario which complicates diagnosis (possible confusion with congenital myasthenic syndromes or certain myopathies) and delays finding an effective treatment.

- During a workshop organised in the Netherlands in 2024 by the European Neuromuscular Centre (ENMC), disease experts and patient representatives created a "decision tree" to help diagnose seronegative myasthenia gravis. This diagnosis is made based on the presence of both a neuromuscular transmission defect (demonstrated by electromyography and a cholinesterase inhibitor test) and an immune mechanism of the disease (evidenced by the improvement of symptoms on immune-targeted medication).

Evoli A et al. Neuromuscul Disord. 2024

Debated and confirmed manifestations

The importance of considering non-motor symptoms

People with myasthenia gravis experience smell disorders, headaches, anxiety, depression and sleep disorders more often than people without the disease. This is the conclusion of a Turkish study conducted in 70 participants.

- Although the mechanisms underlying these non-motor manifestations have yet to be identified, they can all impact quality of life if they are not detected and treated.

Tekeşin A et al. Turk J Med Sci. 2024

Cognitive impairment, with or without depression

Does myasthenia gravis cause cognitive impairment? The answer seems to be more no according to new results published in mid 2024 concerning 33 myasthenia gravis patients aged 24 to 70 years old. Their cognitive functions, mood (depression) and chronotype (more "morning lark" or "night owl") were evaluated in the morning and the evening of the same day.

- This study found no significant differences between the participants, or in each participant over the course of the day. However, those on antidepressants obtained better results in attention and working memory

***Cognitive functions** are the mental processes that enable us to acquire and use knowledge (perception, attention, memory, information language, problem solving, decision making, ….).*

tasks. The treatment of mood disorders could therefore improve cognitive function in myasthenia gravis patients.
Witkość-Dębczyńska M et al. Postep Psychiatr Neurol. 2024

In Spain, a team of neuropsychologists showed photos of anonymous faces to 52 adults with myasthenia gravis and 40 healthy volunteers.

- The study found that the myasthenia gravis patients had more difficulty recognising the same face presented in different ways (different lighting, front, side or partial views of the face...) than the adults in the control group. They were also less successful in identifying faces expressing fear, happiness, disgust, surprise and anger. However, they were better at recognising sadness. While the reason for these difficulties remains to be determined, it can be said that they are not linked to levels of anxiety or depression.

García-Sanchoyerto M et al. Healthcare (Basel). 2024

Urinary problems that should not be ignored

In Denmark, the HAP-PEE study was conducted in nearly 700 young girls and women aged 12 to 89 years old with a neuromuscular disease, including myasthenia gravis.

- Thirty-nine percent of them found going to the toilet when not at home problematic, and 35% wasted a lot of time and energy planning their toilet visits before leaving the house. A quarter avoided going to the toilet when out and about, including those able to walk and climb stairs, suggesting that this problem goes beyond just a question of accessibility.

The participants adopted various strategies in order to avoid having to use the toilet when not at home, such as refraining from drinking.

- These difficulties impacted the social lives of a third of the participants, imposing limits on them, particularly when it came to going to school or work, visiting friends and travelling.

They also affected their health (for example, 17% experienced recurrent urinary tract infections). However, only 5% of the respondents were referred to a specialist for evaluation (in urology, or, even better, in neuro-urology).
Werlauff U et al. J Neuromuscul Dis. 2024

Mental health suffers

During the Journées de la Société Française de Myologie (annual meeting held by the Société Française de Myologie [French Society of Myology]) in November 2024, Dr Saskia Bresch (neurologist, Nice) shared the results of a survey distributed with the help of the Groupe d'intérêt Myasthénies AFM-Téléthon.

- Only 15% of the 190 respondents were being treated by a psychologist (11%) or a psychiatrist (4%), even though 96% of them reported that the disease had a psychological impact on them. This was caused by the fluctuating and unpredictable nature of myasthenia gravis, anxiety about the future and the progression of the disease, a feeling of anger and injustice but also frustration with healthcare professionals who do not understand or believe them.

A third of the respondents reported that they struggled to talk to their doctor about these problems.
S Bresch. JSFM 2024

Considering osteoporosis in order to prevent it

Myasthenia gravis treatment often involves corticosteroids. However, these drugs can cause osteoporosis (loss of bone density) and therefore fractures. This risk of osteoporosis is at its highest during the first year of treatment.

▪ A group of 57 patients on corticosteroid therapy for a neurological autoimmune disease or myasthenia gravis (16 patients) received a drug to prevent the risk of fracture associated with osteoporosis. Some received a drug from the bisphosphonate family (34 people) while others received denosumab (23 people).

During the six-year follow-up period, bone density (typically measured at the lumbar vertebrae and hips) improved more in the denosumab group than in the bisphosphonate group.

Handa H et al. Intern Med. 2025

HAS guidelines for corticosteroid therapy

According to the HAS (Haute Autorité de Santé [French National Authority for Health]), preventive treatment for osteoporosis should be considered when the dose of corticosteroids reaches or exceeds 7.5 mg per day of prednisone equivalent and the duration of treatment is expected to last longer than three months or has already been taken for more than three months.

"Steroid-induced osteoporosis" can be prevented by:

▪ calcium supplementation (if dietary intake is insufficient) and vitamin D supplementation (if blood levels are low), regular exercise and giving up smoking,

▪ drugs such as bisphosphonates and denosumab (routine for postmenopausal women and men over the age of 50)

Les médicaments de l'ostéoporose [Osteoporosis drugs], HAS, updated 24 January 2023

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Keep up to date with myasthenia gravis research news throughout the year on the AFM-Téléthon website:

www.afm-telethon.fr/en