Whole body muscle MRI in Myasthenia gravis

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Main objective: 1. To determine the feasibility of measuring fat replacement, atrophy and inflammation using MRI in several muscle groups in Myasthenia gravis patients, by determining scan quality and the difference in these parameters between MG...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52030

Source
ToetsingOnline

Brief title
Whole body muscle MRI in Myasthenia gravis

Condition

- Neuromuscular disorders

Synonym
Myasthenia, Myasthenia gravis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MRI, Muscle, Myasthenia gravis, Whole-body

Outcome measures

Primary outcome

The main study parameters are fat fraction, the muscle volume and the amount of

positive T2-STIR lesions.

Secondary outcome

The secondary study parameters are the scan protocol toleration by patients,

the visibility of all muscles and the robustness of the quantitative data.

Study description

Background summary

Myasthenia gravis (MG) is a chronic auto-immune with antibodies targeting proteins in the neuromuscular junction, causing muscle weakness. Early treatment could prevent generalisation of muscle weakness in MG. Therefore, there is a clinical need to understand the clinical and subclinical involvement of muscles to better understand the pattern of muscle involvement and the process of generalisation. Furthermore, MG is treated with immunosuppressant drugs like corticosteroids. Unfortunately, long term steroid use carries a considerable risk of side effects. A clinical need exists to better monitor the treatment response and the potential benefit of intensifying treatment for specific muscles.

It is previously shown that in a specific group of MG patients, with MuSK antibodies, atrophy and fat replacement of the bulbar muscle can be observed. We have previously shown that eye muscles show fat replacement in most MG patients. The extent in which muscles throughout the body can be structurally damaged by the disease is unknown. Therefore, we propose a study to map the extend of atrophy, fat replacement and inflammation of the muscles.

The amount of MRI-detectable muscle damage in muscles of MG patients can be used as a biomarker to quantify disease activity and disease progression. This could provide valuable information for choosing the correct treatment modality and avoiding overtreatment with immunosuppressive drugs at the risk of severe

side-effects.

Study objective

Main objective:
1. To determine the feasibility of measuring fat replacement, atrophy and inflammation using MRI in several muscle groups in Myasthenia gravis patients, by determining scan quality and the difference in these parameters between MG patients and healthy controls.

Secondary Objectives:
2. To determine if the MRI findings correlate with the clinical pattern of muscle weakness as measured by the QMG muscle test and as reported by MG-ADL.
3. To determine the patient experience of the proposed MRI protocol.
4. To confirm the measures of fat replacement, atrophy and inflammation using MRI in refractory MG patients with clinical signs of atrophy.
5. To determine the change in MRI findings of fat replacement, atrophy and inflammation due to clinical treatment in refractory MG patients

Study design

This study in an observational study. Patients will undergo one MRI scan (~60 minutes). Hereafter, patients will be asked to fill in the MRI acceptability questionnaire, the IPAQ-sf questionairre, the mg-AGL questionnaire and muscle weakness/fatigability will be tested with a QMG (~30 minutes). The refractory patients will be asked for a follow-up visit after a clinical treatment period.

Study burden and risks

This study has no invasive procedures. Subjects with contraindications for MRI will be excluded. There are no known risks known associated with the use of MRI. Participants have no personal benefit from participating in this study. However, the results study may contribute to the understanding of the course of the disease and predictability of therapeutic response in all MG patients.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific

Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Definitive diagnosis of MG defined as the presence of serum autoantibodies (anti-acetylcholine receptor [AChR], anti-muscle specific tyrosine kinase [MuSK])

Exclusion criteria

- Subjects who are not legally capable
- Subjects under the age of 18
- No (other) diagnosis of neuromuscular disease or chronic lesions to the musculoskeletal system
- Contraindications to MRI scanning
- In healthy controls: the use of anabolic steroids

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-09-2021
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO

Date:	19-03-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	04-03-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL75117.058.20