MRI of eye muscles in myasthenia gravis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23441

Source
NTR

Brief title
MYMRI

Health condition

Myasthenia gravis, Graves' orbitopathy

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Not Applicable

Intervention

Outcome measures

Primary outcome

(1) QMRI parameters (muscle fat fraction, muscle inflammation, muscle volume) which are hypothesized to differ between MG
patients and the healthy/disease controls for diagnostic value.
(2) For the second objective comparing recently diagnosed and chronic MG patients for exploring the pathophysiology

Secondary outcome

(3) For the third objective comparing the gMRI parameters in time in the recently diagnosed MG group to measures of severity of
disease to assess the predictive value for treatment response.
(4) For the fourth objective comparing gMRI parameters to functional measures in all groups for exploring the relationship with the
symptoms

Study description

Background summary

The auto-immune disease myasthenia gravis (MG) affects the neuromuscular junction (NMJ) and commonly starts with weakness of the extra-ocular muscles (EOM). In patients with pure EOM symptoms and no acetylcholine receptor (AChR) antibodies, diagnosis is difficult and time-consuming. This causes significant burden for patients and delays effective treatment.

Furthermore, treatment usually consists of immune suppressant medication, of which corticosteroids are the most commonly prescribed. Unfortunately, long term steroid use carries a considerable risk of unacceptable side effects. While immune suppressant treatment leads to a significant improvement in the majority of patients, 15% show only a moderate improvement or no improvement at all after treatment with corticosteroids.

Using magnetic resonance imaging (MRI), we have shown structural changes in the EOM of a small group of MG patients, which has not been described in literature before and was not expected based on the current knowledge of the pathophysiology. We hypothesize that these changes are specific to MG and are sensitive to treatment and therefore can be used in differential diagnosis and to predict treatment response. Therefore, we aim to develop a novel diagnostic paradigm for AChR negative MG and a predictor for treatment efficacy in all MG patients by systematically comparing qMRI parameters of the EOM in clearly defined clinical groups of MG patients to healthy and disease controls (other neuromuscular diseases and Graves’ orbitopathy (GO)) and over time.

Study objective

We hypothesize that structural changes in the eye muscles are specific to MG and are sensitive to treatment and therefore can be used in differential diagnosis and to predict treatment response.

Study design

01-Jul-2022

Contacts

Public
Leiden University Medical Center
Kevin Keene

0715297583
Scientific
Leiden University Medical Center
Kevin Keene

0715297583

Eligibility criteria

Inclusion criteria

Recently diagnosed MG patients
- Definitive diagnosis of MG defined as the presence of serum autoantibodies (anti—acetylcholine receptor [AChR], anti-muscle specific tyrosine kinase [MUSK])
- Start of symptoms was less than a year ago
- No corticosteroid treatment received in the past year
- No TSH-receptor auto-antibodies, no laboratory signs of thyroid dysfunction (T4, TSH),
Chronic MG patients
- Definitive diagnosis of MG, defined as described above
- Persisting symptoms of diplopia
- Start of symptoms was more than a year ago
- No TSH-receptor auto-antibodies, no laboratory signs of thyroid dysfunction (T4, TSH),
Seronegative MG patients
- Clinical diagnosis of MG with asymmetric, fluctuating and fatigable muscle weakness and at least one abnormal neurophysiological test, indicative of neuromuscular dysfunction (repetitive nerve stimulation or single fiber EMG)
- No serum autoantibodies (anti—acetylcholine receptor [AChR], anti-muscle specific tyrosine kinase [MuSK])
- No TSH-receptor auto-antibodies, no laboratory signs of thyroid dysfunction (T4, TSH)

Healthy controls
- No symptoms of diplopia
- No ophthalmopathy
- No prior systemic treatment with corticosteroids, Patient controls: Graves' orbitopathy

- Definitive diagnosis of Graves' orbitopathy, Patient controls: Other neuromuscular disease
- Definitive diagnosis of a neuromuscular disease other than Myasthenia gravis

Exclusion criteria

- Subjects who are not legally capable
- Subjects under the age of 18
- Contraindications to MRI scanning, including:
o Claustrophobia
o Pregnancy
o Pacemakers and defibrillators
o Nerve stimulators
o Intracranial clips
o Metallic fragments
o Cochlear implants
o Ferromagnetic implants
o Hydrocephalus pump
o Permanent make-up
o Tattoos above the shoulders
o Piercings (unless they can be removed)
o Subjects who cannot keep their head still (eg. Tremor, Parkinson's disease)
o Severe physical restriction (completely wheelchair dependent)
❑ In the case of uncertainty about the MRI-contraindications, the MR-safety commission of the radiology
department will decide whether this subject can be included in the study or not.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-07-2019
Enrollment:	130
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48436
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8291
CCMO	NL68612.058.18
OMON	NL-OMON48436

Study results