Capturing key symptoms using smartphone recordings in patients with myasthenia gravis.

Published: 18-11-2024
Last updated: 31-01-2025

The main objective is to explore whether digital features of dysarthria, dysphonia, proximal arm fatigue and ptosis can differentiate between participants with and without MG.

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

Summary

ID

NL-OMON57109

Source
ToetsingOnline

Brief title
CAPTURE-MG

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: Huma Therapeutics Limited

Intervention

Keyword: Artificial intelligence, Myasthenia gravis, Smartphone

Outcome measures

Primary outcome

The primary endpoint is to explore whether digital features of dysarthria, dysphonia, proximal arm fatigue and ptosis can differentiate between participants with and without MG.

Secondary outcome

a) To assess the correlation between digital features of dysarthria, dysphonia, proximal arm fatigue and ptosis in MG patients and disease severity as measured by the MGC score.

b) To assess the correlation between digital features of dysarthria, dysphonia, proximal arm fatigue and ptosis in MG patients and their quality-of-life as measured by the MG-ADL questionnaire.

c) To assess the performance of automated signal processing of speech recordings collected through smartphone microphone for detection of dysarthria and dysphonia, in comparison to assessment by accredited clinicians.

d) To assess the performance of automated measurement of proximal arm-fatiguing exercises through computer vision techniques applied to smartphone camera recordings for detection of proximal arm muscle weakness and fatigability, in comparison to assessment by accredited clinicians.

e) To assess the performance of automated measurement of ptosis-provoking exercises through computer vision techniques applied to smartphone camera recordings for detection of ptosis, in comparison to assessment by accredited

clinicians.

f) To assess the correlation between digital features of dysarthria, dysphonia, proximal arm fatigue and ptosis in MG patients and their level of fatigue as measured by the Checklist Individual Strength (CIS-) fatigue subscale.

Study description

Background summary

Myasthenia Gravis (MG) is a chronic antibody-mediated auto-immune disease affecting the neuromuscular junction. MG is characterized by fluctuating weakness and fatigability of the skeletal muscles. While a subset of patients (15%) experience only ocular symptoms, the majority (85%) experience generalized manifestations. Several outcome measures are used to assess MG in clinical trials and in practice, such as the MG-QoL 15r and MG-ADL. Digital technologies as an alternative solution to support the monitoring and management of patients with neurological disorders, are becoming increasingly popular. Digital medicine, specifically mobile health applications, has the potential to support the management of MG by providing remote patient monitoring and data collection. Two promising applicable techniques are computer vision and vocal analysis, which both involve using machine learning algorithms applied to either images and videos captured by the smartphone camera or audio recorded by the smartphone microphone, respectively. Computer vision can be used to monitor MG patients for ocular symptoms such as diplopia or ptosis or may be used to assess physical activity, endurance and mobility in MG patients. Audio or speech analysis solutions hold the potential to identify and quantify speech disturbances in MG, such as dysarthria and dysphonia. These data can be used in concert to monitor disease progression, track treatment response, assess the effectiveness of physical therapy or rehabilitation, and identify early signs of relapse, remotely, without the need for live clinical support. Additionally, these technologies could provide patients with real-time feedback on their speech and motor functions to help monitor symptoms and self-assess disease status, adjust communication strategies, improve self-management, and reduce the burden of frequent clinic visits. It is hypothesized that there are distinct digital biomarkers that differentiate MG patients from healthy controls and that these biomarkers will correlate with MG severity scores and quality of life. We expect that a remote solution that empowers patients to track their disease status and facilitates the documentation of their experiences, would offer noteworthy advantages.

Study objective

The main objective is to explore whether digital features of dysarthria, dysphonia, proximal arm fatigue and ptosis can differentiate between participants with and without MG.

Study design

This study will make use of a cross-sectional design of MG patients and non-MG participants to quantitatively assess key MG symptoms, and to explore the applicability of machine learning algorithms to their measurement.

Study burden and risks

Due to the cross-sectional design, participants will only have to visit Leiden University Medical Center (LUMC) once. For patients already treated in the LUMC, we will try to align this visit with a standard clinical appointment.

After inclusion, all baseline data, consisting of demographics, clinical history and a number of questionnaires (three for MG participants, one for non-MG participants), will be collected. The symptom-specific assessments are performed in a standard order, with the most fatiguing task (i.e. proximal arm fatigue static assessment) last. We estimate the visit will take a total of 60 minutes.

This study is considered to be low risk. Withholding pyridostigmine for a limited period is part of standard care of MG (before investigations or clinical assessments) and does not affect long term clinical outcome. MG participants will consent to withhold pyridostigmine for 12 hours prior to the study visit if they are on this treatment and restart it after the visit. As this is a non-interventional, observational study where only questionnaire-based and non-contact digital data are being collected, the only source of marginal risk relates to data protection and confidentiality, including arrangements for the transfer and storage of data. Given it would not be possible to deidentify the digital audio or video data while maintaining the requisite integrity for data analysis, we will seek explicit consent for the use of this information in this identifiable format.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL

Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age >= 18 years
- Ability to understand the requirements of the study and provide written informed consent.

Inclusion criteria for MG participants only
- A clinical diagnosis of myasthenia gravis (ocular or generalized) with the typical fluctuating muscle weakness and at least one of the following:
--- positive serologic test for AChR or MuSK antibodies;
--- an abnormal electrodiagnostic test: repetitive nerve stimulation (RNS) or single-fiber electromyography (SFEMG).
- MGFA Clinical Classification of disease severity I-IV.
- Subjects have at least one of the symptoms of interest (namely dysarthria, dysphonia, proximal arm fatigue and/or ptosis).

Inclusion criteria for non-MG participants only
- Subjects are not diagnosed with and have no clinical suspicion of MG.
- Subjects do not have a medical history of any of the symptoms of interest (namely dysarthria, dysphonia, proximal arm fatigue and/or ptosis).

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Not willing to be audio-recorded for the study assessments.
- Not willing to be video-recorded for the study assessments.
- Subjects currently taking part in a clinical trial of an Investigational Medicinal Product.
- Subjects who have used an immediate release pyridostigmine-based medication in the 12 hours prior to their participation and participants on prolonged release pyridostigmine.
- Subjects have cognitive or physical limitations that, in the opinion of the investigator, limits the subject's ability to complete study procedures.

Exclusion criteria for MG participants only
- Subjects with an upper-limb amputation or who are non-verbal.
- Subjects with a diagnosed neurological disease resulting in muscle weakness, other than MG.

Exclusion criterion for non-MG participants only
- Limitation of upper limb mobility or speech impairment of any cause.

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:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	225

Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	18-11-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-01-2025
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	NL86693.058.24