The face of neuromuscular dysfunction: artificial intelligence for the analysis of video data of facial movement, with a focus on Myasthenia Gravis

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Primary objectives: To determine and compare the diagnostic yield of two different methods (FaceReader technology and a deep learning model specifically developed for video data) to analyse facial weakness from video recordings (04:00m) with...

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

Summary

ID

NL-OMON52702

Source
ToetsingOnline

Brief title
The face of Myasthenia Gravis

Condition

- Neuromuscular disorders

Synonym
myasthenia gravis; 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: facial recognition, machine learning, myasthenia gravis

Outcome measures

Primary outcome

1. Diagnostic yield, expressed as sensitivity, specificity and area under the curve of a receiver-operator curve (ROC) of the FaceReader algorithm, using quantitative data of facial weakness expressed in Action Units (AU), ranging between 0 (no activation) and +1 (maximal activation). Raw data from FaceReader provides the results of 20 AU*s corresponding with 20 different facial movements of 20 facial muscles based on the Facial Action Coding System (FACS). We will calculate the diagnostic yield of individual muscles and combinations of muscles to differentiate between healthy controls and MG and between different grades of MG disease severity.

2. Diagnostic yield, expressed as sensitivity, specificity and area under the curve of a receiver-operator curve (ROC) of a working narrow deep learning model to differentiate between healthy controls and MG and between different grades of MG disease severity.

Secondary outcome

1. Detection of medication effects by obtaining multiple videos (longitudinal) in a subset of patients. The QMG score is the parameter for change in disease severity. A previous study found a minimal clinically important difference (MCID) in QMG score of >=2 for a baseline QMG score between 0 and 16. For a baseline QMG score >16 the MCID is >=3 points change in QMG score4. For change

in severity, our aim is to detect an intra-participant difference in case of a

change in QMG >=2 or >=3, depending of baseline QMG score.

2. A comparison of the diagnostic yield of FaceReader parameters and

classification by the deep learning model.

Study description

Background summary

Myasthenia Gravis (MG) is an autoimmune disorder (AID) with antibodies against the NMJ, resulting in various degrees of muscle fatigability and weakness. All striated muscles can be involved, although the extra-ocular muscles are most commonly affected, giving rise to a fluctuating ptosis and diplopia. Facial muscles are also commonly affected, resulting in eye closure weakness, difficulty chewing and swallowing or speech impairments. Antibodies against the acetylcholine receptor (AChR) are present in over 80% of generalized MG patients. In the pure ocular form, AChR antibodies are detectable in nearly 50% of all patients. In approximately 4%, antibodies against the postsynaptic muscle-specific receptor tyrosine kinase (MuSK) are found and in 15% of the patients with generalized disease, no serum antibodies are detected. Approximately 15% of AChR MG patients has a thymoma, in which case the disease can be classified as a paraneoplastic syndrome2. With a prevalence of 1 to 2 per 10.000, MG is considered a rare disease.
The rarity of MG can make it difficult to diagnose, specifically for general Neurologists who are likely to encounter a patient with MG only a handful of times throughout their career. In addition, the fluctuating nature of the disease makes it difficult to make appropriate treatment decisions, especially as patients throughout the country are usually treated at one specialized center (in the Netherlands, the LUMC). Currently, patients who are in doubt whether they are experiencing an exacerbation have to make an appointment and travel for several hours to undergo assessment by their specialized Neurologist. An objective, reliable biomarker for disease severity that can be used at home would therefore greatly improve quality of life for many MG patients. Emerging possibilities in modern technologies can support doctors with all kinds of medical challenges, like offering diagnostic support, treatment decisions or patient follow-up. A technology of special interest for this study is advanced facial recognition. We aim to study the ability of existing software (FaceReader, Noldus) versus a deep learning model specifically developed for this purpose by the group of Jan van Gemert at the TU Delft to differentiate between healthy controls and patients with MG and

between MG patients with different levels of disease severity.

Study objective

Primary objectives:
To determine and compare the diagnostic yield of two different methods (FaceReader technology and a deep learning model specifically developed for video data) to analyse facial weakness from video recordings (04:00m) with different standardized facial expressions to:
1. Differentiate between MG patients and healthy controls.
2. Differentiate between mild and moderate to severe disease severity.

Study design

observational prospective case-control study.

Study burden and risks

patients and healthy volunteers will be asked to participate in a one-time video recording of 04:00 minute, a subgroup of MG will be asked to undergo multiple videos over time. There are no risks involved in participating.
MG patients who do not undergo a QMG for their standard care will be asked to undergo a QMG test. This is a clinical test for establishing disease severity and is widely used in clinical practice. Performing a QMG will take 5 minutes and consists of an assessment of muscle fatigability. There are no risks involved, except for a minor risk of discomfort when patients with difficulties swallowing are asked to drink half a cup of water. This risk will be minimized by leaving out this item when known difficulties with swallowing are present, as is common clinical practice. The benefit of participation is the possible future development of a diagnostic tool for physicians and the possibility of improved clinical care through automated remote monitoring of disease severity through video recording.
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

definite diagnosis of myasthenia gravis (positive serologic test or electrophysiological support or positive neostigmine test)

Exclusion criteria

Participants with active Graves* disease

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2021
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-11-2022
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	NL74427.058.20