Validation of the Quantified Myasthenia Gravis strength score (QMG Score): is it both sensitive and specific?

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What values are normal in healthy controls for endurance and force? Are these values the same for men and female? What is the effect of age to these normal values? What are endurance and force for patients with myasthenia gravis? Are there specific...

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

Summary

ID

NL-OMON31839

Source
ToetsingOnline

Brief title
Validation of the QMG Score

Condition

- Neuromuscular disorders

Synonym
myasthenia MG

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: endurance, force, myasthenia gravis, neuromuscular disease

Outcome measures

Primary outcome

QMG Score and QMA Score: normal values for different diseases, adapted for age

and gender.

Secondary outcome

QMG/QMA ratio: differences between helathy controls and patients? difference

between MG and other neuromuscular diseases?

Study description

Background summary

Myasthenia Gravis is a disease characterized by muscle weakness and fatigue of voluntary muscles. Progressive weakness during sustained exercise is considered characteristic for MG and its presence is used as a diagnostic tool. Proper muscle diseases, like IBM or myotonic dystrophy, are characterized by weakness but not by a lack of endurance, or so textbooks and experts say.
These teste, measuring muscle force and endurability, are scarcely validated.

Study objective

What values are normal in healthy controls for endurance and force? Are these values the same for men and female? What is the effect of age to these normal values?
What are endurance and force for patients with myasthenia gravis? Are there specific endurance and force patterns for patients with other forms of muscle weakness, like myotonic dystrophy, inclusion body myositis or other neurological diseases?

Study design

The research protocol consists of two questionnaires (patient characteristics and ACTIVLIM) and two tests (QMG score and QMA score).
The first questionnaire contains questions regarding descriptive patient

characteristics and additional factors that may influence muscle strength or endurance(addendum 4). The second questionnaire, ACTIVLIM, (addendum 5) comprises of 22 short questions.
The QMG Score (addendum 1) involves a standardized test protocol (addendum 2). The items are recorded in the same order for all patients. The endurance tests in the present version of the QMG Score now have a predefined maximum score, above which endur-ance is considered normal. To test this assumption, the period of time during which peo-ple are asked to perform the task will be doubled (for example, subjects will be asked to hold their leg stretched for 200 instead of 100 seconds). A hand-held dynamometer will be used for patient*s grip strength.
The QMA Score tests the maximum force of patients of biceps, triceps, quadriceps femoris and hamstrings muscles of both sides.

Study burden and risks

40 minutes, once. In MG patients short-term withdrawal of pyridostigmin just prior to testing is not harmful, although it might be uncomfortable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

myasthenia gravis
neurological disease, that affects muscle strength
age over 12 years old

Exclusion criteria

non-neurological disorder that will affect muscle strength testing (eg rheumatoid arthritis)
combination of different disorders with effect on muscle strength

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	420
Type:	Actual

Ethics review

Approved WMO Date:	25-11-2008
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL20326.058.07