A comparison study of Dutch and Norwegian Myasthenia Gravis patients: epidemiological and clinical aspects.

Published: 30-09-2011
Last updated: 29-04-2024

Objective: to identify potential predisposing and modifying factors of MG in order to improve understanding of the mechanisms of disease, diagnostics and treatment.

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

Summary

ID

NL-OMON35739

Source
ToetsingOnline

Brief title
FIGHT-MG

Condition

- Neuromuscular disorders

Synonym
muscle disease, serious muscle weakness

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Europeese Unie;FP7 programma project nummer 242210

Intervention

Keyword: Epidemiology, Myasthenia Gravis, Quality of life, questionnaire

Outcome measures

Primary outcome

Main study parameters/endpoints:

Primary endpoint: Comparison of potential predisposing and modifying factors

between Dutch and Norwegian MG patients.

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Secondary outcome

Secondary endpoint: Comparison of demography, quality of life and differences

in medical treatment between Dutch MG patients and Norwegian MG patients

Study description

Background summary

Myasthenia Gravis or the Lambert-Eaton myasthenic syndrome are an acquired chronical autoimmune neuromuscular disorders. The pathogenesis of Myasthenia Gravis is unclear and deserves further investigation. Prevailing theories are involving complex immunogenetic, environmental and hormonal agents. Epidemiological studies of Myasthenia gravis patients across Europe involving a large number of patients will improve the knowledge of clinical, psycho-social and environmental factors affecting the course of MG.

Study objective

Objective: to identify potential predisposing and modifying factors of MG in order to improve understanding of the mechanisms of disease, diagnostics and treatment.

Study design

Study design: cross sectional cohort study

Methods: By means of a self- administered questionnaire (E-MG questionnaire) and SF-36.

Study burden and risks

Nature and extent of the burden and risks associated with participation is considered minimal (one questionnaire has to be filled in). There are no direct benefits for the participant, but with this information we hope to optimize the diagnostics and treatment in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

criteria 1 and 2 or 1 and 3 have to be fulfilled
1. Clinical weakness compatible with a from of myasthenia
2. Electromyographic evicence consistent with a neuromuscular transmission defect
3. Elevated serum antibody levels against ACHR, MuSK or VGCC

Exclusion criteria

Age of < 18 years
Lack of both criteria 2 and 3

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	30-09-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date:	30-01-2012
Application type:	Amendment
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	NL36673.058.11