Prolonged repetitive nerve stimulation (RNS) in myasthenia gravis (MG) and Lambert-Eaton myasthenic syndrome (LEMS): quantitative and relevant.

Published: 11-10-2007
Last updated: 09-05-2024

Is it possible to stimulate a eye muscle or underarmmuscle for a prolonged time in a painless way and is this information contributory to make the diagnosis and grade clinical in MG and LEMS?

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

Summary

ID

NL-OMON31264

Source
ToetsingOnline

Brief title
Prolonged RNS in myasthenia

Condition

- Neuromuscular disorders

Synonym
myasthenia MG LEMS

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: LEMS, MG, RNS

Outcome measures

Primary outcome

CMAP-amplitude and change of amplitude after prolonged stimulating and

recording. Is hte pattern different between controls itselves and between

controls and patients?

Secondary outcome

Is the technique painless indeed?

Study description

Background summary

RNS is used for the diagnosis of MG and LEMS. Unfortunately it seems insufficiently able to mimick the "normal" situation of our body muscles to enlighten the pathophysiologic mechanism of weakness in patients. Clinical protocols used nowadays to diagnose myasthenia require high-frequency stimulation (over 30Hz) which is very painful. A painless technique to stimulate at high frequencies will improve diagnostic sensitivity and will diminish paitent's burden.

Study objective

Is it possible to stimulate a eye muscle or underarmmuscle for a prolonged time in a painless way and is this information contributory to make the diagnosis and grade clinical in MG and LEMS?

Study design

A thin needle is inserted subcutaneously besides the lateral eye or proximally in the m. extensor digitorum communis. Stimulating (3 Hz, about 3-6 mA) the tip of the needle is moveduntill visible contractions of forehead or underarm are seen. The needle is fixated. In our experience stimulation itself is not

limited by pain.
A reliable and optimal CMAP-amplitude is determined. The 'black' (negative entrance) as well as the 'red' (positive entrance) electrode are repositioned to achieve this.
After obtaining the CMAP-amplitude the frequency is increased to 10 Hz and recorded for three minutes. All responses are recorded. The recording will be repeated for 30Hz and 50 Hz, both three minutes.

Study burden and risks

30 minutes, once. At the site of insertion a bruise might remain for some days.

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

over 18 years old
MG: clinical signs and symptoms of MG, positive for anti-AChR antibodies and characteristic RNS EMG abnormalities (decrement over 10%) or abnormal Single Fibre EMG.
LEMS: clinical signs and symptoms of LEMS, positive for anti-VGCC antibodies and characteristic RNS EMG abnormalities (decrement over 10% and increment over 60%) or abnormal Single Fibre EMG.

Exclusion criteria

anticoagulant drugs
muscle and nerve diseases or diseases predisposing to nerve or muscled isease, for example diabetes mellitus

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

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	NL19304.058.07