

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

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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?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Neuromuscular disorders
<b>Study type</b>	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 the pattern different between controls themselves 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 mimic 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 patient's burden.

### **Study objective**

Is it possible to stimulate a eye muscle or underarm muscle 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 moved until 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**

### **Public**

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### **Scientific**

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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 muscle disease, 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