Cyclic alterations of Spinal Excitability in patients with Perodic Limb Movements during Sleep and Restless Legs

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Ethical review	Approved WMO
Status	Pending
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON31054

Source
ToetsingOnline

Brief title
CPR

Condition

- Sleep disturbances (incl subtypes)

Synonym
Restless Legs Syndrome / Periodic Limb Movement during Sleep

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Interne fondsen van de afdeling Klinische Neurofysiologie van het LUMC

Intervention

Keyword: H-reflex, PLMS, RLS

Outcome measures

Primary outcome

Amplitude of the H-reflex during a period of complaints of RLS as well as

during periodic limb movements during sleep.

Secondary outcome

None

Study description

Background summary

The Restless Legs Syndrome (RLS) is a disorder of the central nervous system, leading to complaints of dysesthesia or paresthesia in the legs or, less often, in the arms. Typically, complaints occur in the evening and can be relieved by movement of the affected limbs.
In approximately 80% of the patients with RLS, periodic leg movements occur during sleep (PLMS). These muscle contractions last for 0.5 to 5 seconds and are repeated every 20 to 30 seconds. These movements often lead to some arrousal and may therefore cause complaints of excessive daytime sleepiness.
Since both RLS, sensory complaints during wake, and PLMS, a motor phenomenon during sleep, share a distinct periodic character, they are possibly caused by cyclic suppresion of spinal excitability.

Study objective

The aim of this study is to seek evidence that such cyclic suppression exists. For this purpose, we will use the Hoffmann- or H-reflex, an electrically evoked reflex. By stimulating the tibial nerve in the knee, the alpha motor neuron in the spinal cord is activated. This motor neuron sends a signal back, causing contraction of the calf, which can be measured by electromyography (EMG). The amplitude of this signal is the resultant of exciting and inhibiting influences on the alpha motor neuron in the spinal cord. Therefore, cyclic changes in spinal excitability are reflected in the amplitude of the H-reflex.

Study design

Prospective observational study

Study burden and risks

Stopping all medication influencing RLS and/or PLMS two weeks prior to the study may lead to an increase in complaints, but this will not cause any damage tot the patients' health. Furthermore, this increase in complaints is completely reversible when medication is restarted. All used registration methods, the H-reflex as well as sleep registration techniques, have been used worldwide for decades and are completely safe.

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

Daily complaints of idioathic Restless Legs with a minimum of 15 per hour on the Periodic Limb Movement Index

Exclusion criteria

Secondary RLS

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	0
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	NL17454.058.07