Voluntary motor activity in Restless Legs Syndrome and Periodic Limb Movements in Sleep

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The aim of this study is to investigate the differences between RLS and PLMS.

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

Summary

ID

NL-OMON36343

Source
ToetsingOnline

Brief title
Motor activity in RLS and PLMS

Condition

- Sleep disturbances (incl subtypes)

Synonym
Periodic Limb Movements in Sleep, Restless Legs Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Motor activity, Periodic Limb Movements in Sleep, Restless Legs Syndrome, Sensorimotor integration

Outcome measures

Primary outcome

Voluntary fine motor activity will be studied using a manipulandum: a joystick-like device that permits movements in the wrist. Performance (speed, position relative to the manipulandum and position relative to the task) will be compared between groups and controls.

Transcranial magnetic stimulation (TMS) will be used to study sensorimotor integration and intracortical inhibition.

Secondary outcome

Not applicable.

Study description

Background summary

Periodic Limb Movements during Sleep (PLMS) are repetitive, stereotypic, and involuntary dorsiflexion movements of the lower limbs during sleep. These movements can be monitored by electromyographic registration of leg movements during a sleep study (polysomnography). These movements are present in more than 30% of adults over 60 years of age. Periodic Limb Movement Disorder (PLMD) is the combination of PLMS and insomnia or excessive daytime sleepiness (not otherwise explained). The prevalence of PLMD is not known.

Similar Periodic Limb Movements (PLM) are very common in patients with Restless Legs Syndrome (RLS). RLS is a common neurologic disorder characterized by an irresistible urge to move the legs. The four essential criteria for the diagnosis of RLS are undesirable sensations in the legs that occur before sleep onset; an irresistible urge to move the limbs; partial or complete relief of the symptoms on movement of the limbs and return of symptoms on cessation of the movements. These symptoms may disrupt sleep. The prevalence of RLS has been

estimated to be 10-15% in the general adult European population.

Because of the clinical similarities between RLS and PLMS these terms are often used interchangeably. However only 30% or less of patients with PLMS have RLS.

Untill now, only few studies have been performed to investigate the differences between RLS and PLMS.

Study objective

The aim of this study is to investigate the differences between RLS and PLMS.

Study design

Prospective observational case control study.

Study burden and risks

RLS and PLMS patients will visit the department of neurology of the UMCG twice. The first visit will consist of history taking and (neurologic) physical examination. Afterwards the sleep study (polysomnography, PSG) will be performed. PSG is a noninvasive recording of the biophysiological changes that occur during sleep. The PSG monitors body functions including brain, eye movements, skeletal muscle activation (the PLM) and respiratory effort. Subject sleep at home.
During the second visit the next day, the PSG equipment will be detached, followed by the manipulandum test and TMS.
The manipulandum test is an noninvasive study of the fine motor activity. Participants will held a joystick and have to perform a circular tracking task.
TMS uses a rapidly changing magnetic field to activate the primary motor cortex. This produces muscle activity which can be recorded on electromyography. The most serious complication of TMS is the rare occurrence of seizures. However, this risk is very low and TMS is worldwide considered a safe procedure. Moreover subjects with a tendency for epileptic insults will be excluded.
Peripheral nerve stimulation and electromyographic recordings are standard neurophysiologic examinations and without specific risks.

The control subjects will pay one extra visit for performing actigraphy. Actigrafy is a noninvasive method (a watch-shaped instrument worn on the ankle) for screening for PLM. Controls with an high index for PLM on the actigraphy will be excluded.

Secondarily RLS patients without PLM will be studied. They will pay one extra visit for performing actigraphy as well as the control subjects.

There is no direct benefit for partcipants.

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

Right-handed
Age > 18 years
RLS Patients with PLM:
- fullfilling the criteria for RLS
- Periodic Limb Movement Index (= PLMI) > 25
PLMS patients:
- not fullfilling the criteria for RLS
- PLMI > 25
Normal controls

- not fullfilling the criteria for RLS
- PLMI < 5
RLS patients without PLM:
- fullfilling the criteria for RLS
- PLMI < 5

Exclusion criteria

- other neuropsychiatric diseases
- causes of secondary PLMS such as Obstructive Sleep Apneu Syndrome, reumatoid artritis, anaemia
- centrally active drugs, apart form RLS or PLMS medication
- contra-indications for Transcranial Magnetic Stimulation (pregnancy, elektronic devices such as pacemaker)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	14-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL32708.042.11