Suppression of Restless Legs Syndrome (RLS) by Changes in Afferent Input

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Objective: The aim of the study is to investigate whether afferent sensory input reduces the sensory and motor symptoms in RLS patients. By performing a SomatoSensory Evoked Potential (SSEP) we will also look at the central conduction time of an...

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

Summary

ID

NL-OMON31286

Source
ToetsingOnline

Brief title
SIT-SEP

Condition

- Sleep disturbances (incl subtypes)

Synonym
ekbom's syndroom, restless legs

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: geen

Intervention

Keyword: restless legs syndrome (RLS), somatosensory evoked potentials (SSEP), suggestive immobilisation test (SIT)

Outcome measures

Primary outcome

Primary outcome:

The influence of an electrical stimulus on:

sensory symptoms in RLS measured by *the area under the curve* of the

VAS-scores gained during the three different study conditions.

motor symptoms in RLS measured by *The Periodic Limb Movement Index* gained

during the three different study conditions.

Secondary outcome

Secondary outcome:

Differences in latencies and amplitudes between the SSEP measured before and

after electrical stimulation (as in condition 2, see below).

Study description

Background summary

Rationale: Restless Legs Syndrome (RLS) is characterised by the occurrence of unpleasant and/ or disabling symptoms at rest, associated with an urge to move (motor symptoms). These symptoms begin or worsen during rest or inactivity and occur mostly at evening or night. They are relieved by voluntary movement at least as long as the activity continues. Besides that, a diversity of sensory input may reduce the RLS symptoms. Until now there are no systematic studies on external sensory input reducing RLS symptoms. To gain insight into the pathophysiological mechanism of RLS, we perform a study to test the effect of sensory input on the severity on RLS symptoms.

Study objective

Objective: The aim of the study is to investigate whether afferent sensory input reduces the sensory and motor symptoms in RLS patients. By performing a SomatoSensory Evoked Potential (SSEP) we will also look at the central conduction time of an electrical stimulus in RLS patients.

Study design

Study design: We will conduct pathophysiological study with RLS patients. Measurements will be done during the evening as RLS patients have most complaints during the evening and night. All patients will undergo three study conditions. During these three study conditions patients will undergo the SIT. To measure RLS symptoms patients will be asked to fill in a VAS scoring list. Furthermore involuntary leg movements will be recorded by EMG. Depending on the study conditions, patients will receive an electrical stimulus on both legs. To control for the twitch of the big toe, caused by this electrical stimulus, a third study condition is created in which the stimulus intensity remains the same but the stimulator is moved to prevent the twitch of the big toe. Additionally a SSEP will be made four times during the study. The order in which patients will take the different study conditions will be randomised.

Study burden and risks

Ethical aspects: Two weeks before start of the study patients are asked to stop their medication which will induce return or worsening of RLS symptoms. However, this will not put patients at risk for physical injury whatsoever. Furthermore, patients are asked to come to the Holland Sleep Centre and the Medical Centre Haaglanden for one evening. All of the survey methods used in this study are completely safe and are used in daily clinical practise.

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

Inclusion criteria:
Patient*s age must be between 18-65 years old;
Patients must have definite RLS as defined by the International Restless Legs Syndrome Study Group (IRLSSG). This means that all of the four main criteria must be fulfilled (2);
Patient must have severe RLS as measured by the John Hopkins RLS Severity scale (JHRLSS); score 2 or higher (3);
Patient must score more than 15 on the International Restless Legs Severity Scale (IRLSS) in which item seven is answered with 6-7 days a week (score 4) (7);
Patients are not allowed to receive any treatment for RLS during the study (including benzodiazepines). If patients already received therapy for the RLS they will be asked to stop their medication two weeks prior to the study.

Exclusion criteria

Exclusion criteria:
Patient will be excluded if:
They use medication known to affect sleep or motor behaviour, such as stimulants, hypnotics, neuroleptics or antidepressants;
They have medical conditions known to be associated with RLS, i.e. iron deficiency, peripheral neuropathy, end-stage renal disease, pregnancy, hypothyroidism;
They have other sleep disturbances such as sleep apnoea, narcolepsy, parasomnia or primary or secondary insomnia (other than caused by RLS) as established by patient interview;
They cannot bear the stimulus intensity that is needed for a good reproducible SSEP;
It is not possible to reproduce a SSEP from the posterior tibial nerve on one side or both sides of the leg;

They have neurological (other than RLS) or psychiatric diseases.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-06-2007
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	04-06-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL16647.098.07