Measuring the effects of continuous dopaminergic stimulation on nocturnal movements in Parkinson's disease.

Published: 27-02-2012
Last updated: 30-04-2024

Primary:• To study the effect of rotigotine on nocturnal hypokinesiaSecondary:• To study the possibility of measuring nocturnal hypokinesia and its severity in a home setting• To correlate improvements in sleep quality by rotigotine with changes in...

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

Summary

ID

NL-OMON35536

Source
ToetsingOnline

Brief title
Nocturnal movements and rotigotine in Parkinson's disease

Condition

- Sleep disturbances (incl subtypes)

Synonym
difficulty turning around in bed, nocturnal hypokinesia

Research involving
Human

Sponsors and support

Primary sponsor: Centrum voor Slaapgeneeskunde Kempenhaeghe
Source(s) of monetary or material Support: Ministerie van OC&W,UCB Pharma

Intervention

Keyword: nocturnal movements, Parkinson's disease, rotigotine, sleep quality

Outcome measures

Primary outcome

Position changes over the night.

Secondary outcome

Objective

• Degree of mobility, measured as the speed of the movements

• Total amount of movements

• Score on the motor symptom scale according to the MDS-UPDRS part III

Subjective

• Nocturnal sleep quality

Excessive daytime sleepiness

• Presence of nocturnal akinesia

Study description

Background summary

Parkinson*s disease (PD) is a neurodegenerative disorder that is characterized with motor symptoms such as hypokinesia, rigidity, tremor and postural instability. These symptoms can also be present during the night. Half of the patients with PD have difficulty turning around in bed. This nocturnal hypokinesia is considered as a possible cause of sleep problems in this population. The diagnosis nocturnal hypokinesia is based on the clinical interview. There is a need for a diagnostic devices that measures nocturnal movements, preferably in the home setting. This device can be used in the diagnostic trajectory as well in the evaluation of treatment. Recently the Dynaport Minimod (McRoberts, The Hague) has been developed to register

nocturnal movements. The tri-axial accelerometer has been developed to measure position changes in the night. A validation study with actigraphy and polysomnography concluded that the Dynaport MiniMod is a valid an feasible device for assessing intensity and physical activity and changes of body position during sleep.

Nocturnal hypokinesia is treated with nocturnal dopamine. Sometimes a night-time dose of dopaminergics is adequate, but most of the time slow release dopaminergics are needed. However response fluctuations can negatively influence the treatment. In these cases continuous dopaminergic stimulation is needed, such as rotigotine. Rotigotine treats response fluctuations during the day and studies show that sleep quality measured with questionnaires improves. If the improvement of sleep quality is caused by improved bed mobility has not been studied yet.

Study objective

Primary:
• To study the effect of rotigotine on nocturnal hypokinesia

Secondary:
• To study the possibility of measuring nocturnal hypokinesia and its severity in a home setting
• To correlate improvements in sleep quality by rotigotine with changes in nocturnal hypokinesia

Study design

We will study patients who will recieve rotigotine as a part of their usual care. During three nights, nocturnal movements are being registered with movement sensors, before treatment has started as well as after a stable medication dose of one month. We will also assess sleep quality with questionnaires.

Study burden and risks

The rotigotine patches can, like every other drugs, have side-effects. For rotigotine the most common side-effects are skin reactions on the administartion place, nausea, dry mouth and desoriëntation. Although de movement sensor is small, it is possible that it can interfere with the patients sleep.

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

Patients with idiopathic PD
Patients who will start treatment with rotigotine
Hoehn & Yahr stage II - IV
Subjective sleep problems most likely caused by nocturnal hypokinesia

Exclusion criteria

Other significant causes for nocturnal motor symptoms which are not dopamine-responsive
Previous surgery for PD
Mini- mental state examination score < 25
Concurrent hallucination or psychosis

History of skin hypersensitivity to adhesives or other transdermals

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-05-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	27-02-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL38851.091.11