The effect of Methylphenidate on sleep and circadian rhythm in adult ADHD measured with actigraphy and the dim light melatonin onset (DLMO)

Published: 02-03-2012
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The objectieve of this study is to gain insight into the effect of methylphenidate on sleep and the circadian rhythm in adults with ADHD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Developmental disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON35707

Source
ToetsingOnline

Brief title
The effect of methylphenidate on circadian rhythm in Adult ADHD

Condition

- Developmental disorders NEC

Synonym
Attention deficit/hyperactivity

Research involving
Human

Sponsors and support

Primary sponsor: Pro Persona Veluwe Vallei (Ede)
Source(s) of monetary or material Support: Pro Persona West

Intervention

Keyword: ADHD, Adult, DLMO, Methylphenidate

Outcome measures

Primary outcome

DLMO (Dim light melatonin onset)

Circadian actografic parameters

PAD (phase angle difference)

Secondary outcome

subjective sleepparameters measured with self reporting lists

Study description

Background summary

Previous studies showed that sleep problems are common in adults with ADHD. Treatment with methylphenidate treatment leads to later bedtime and a longer sleep time. However, the methylphenidate-treated patients with ADHD are less likely to wake during the night and reported improved sleep quality.
Falling asleep late may indicate a disturbance of the biological clock, characterized by delayed endogenous melatonin production (DLMO). There is only one study in adults and in one in children which looked at the effect of methylphenidate on the circadian rhythm. These studies show a delayed circadian measured with actigraphy. To understand the effect of methylphenidate in adults with ADHD on the circadian rhythm, this study will not only focus on actigraphic circadian parameters but also on the endogenous melatonin production (DLMO).
This pilot aims to answer the question whether improved sleep, or even worse sleep through the use of methylphenidate is caused by shifting of the circadian rhythm. Maybe in the future before the start of treatment, measuring the DLMO could give a prediction about the effect of methylphenidate on sleep in adults with ADHD.

Study objective

The objectieve of this study is to gain insight into the effect of

methylphenidate on sleep and the circadian rhythm in adults with ADHD.

Study design

Open pilot study

Study burden and risks

The burden for the subjects in time is 185 minutes (questionnaires, DLMO , blood samples, actography. Except for increased risk of hematoma through blood tests, the risks are negligible.

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

Adult ADHD patients between 21-60 years old

Exclusion criteria

Use of medication which influences sleep and/or the endogenous melatonin production
recent traveling within more than one time zone or participation in shift work
Substance abuse
Contraindications for the use of methylphenidate

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2012
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	02-03-2012
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	NL38784.091.11