Influence of methylphenidate on sleep and circadian rhythm in children with Attention-Deficit/Hyperactivity Disorder (ADHD)

Published: 11-12-2007
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Determine the influence of methylphenidate treatment on sleep-wake rhythm and endogenous melatonin rhythm.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON31584

Source
ToetsingOnline

Brief title
MELMET Study

Condition

- Sleep disturbances (incl subtypes)
- Psychiatric disorders

Synonym
Sleep onset insomnia

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei

Source(s) of monetary or material Support: Alle onderzoeken die bij studiepersonen uitgevoerd worden;worden volledig vergoed door de ziektekostenverzekering van de proefpersoon

Intervention

Keyword: ADHD, Circadian rhythm, Dim light melatonin onset, Methylphenidate

Outcome measures

Primary outcome

Primary parameters: 1) sleep latency 2) sleep onset time; 3) total time

asleep; 4) Difficulty falling asleep (from actigraphy and sleep log) and dim

light melatonin onset (DLMO) from salivary melatonin

Secondary outcome

Not applicable.

Study description

Background summary

Disordered sleep is a common phenomenon among children with ADHD. Methylphenidate therapy initiates or worsens sleep onset problems in a substantial percentage of these children. The exact effect of methylphenidate on sleep is unknown, but recent research suggests that methylphenidate may affect sleep-wake rhythm by exerting effects on the biological clock and thereby altering the endogenous circadian rhythm of melatonin.

Study objective

Determine the influence of methylphenidate treatment on sleep-wake rhythm and endogenous melatonin rhythm.

Study design

Observational study in a group of children with ADHD who are assigned to a short cross over trail of methylphenidate/placebo by the paediatricans. Measurements of sleep using actigraphy and sleeplog, and of endogenous melatonin from saliva are performed at baseline and in the second week of the

cross over trail.

Intervention

The first group will be treated with methylphenidate divided over the day in two doses (amount 0.5 mg/kg), the second group will be treated with placebo in the same amount as the first group.

Study burden and risks

The burden of the study is wearing the actometer at night during the study period and chewing on a cotton plug (during 1minute) on 5 different time points at 2 nights in the study period. Normally, in regular clinical practice, these tests are not experienced as very demanding by the patient.

Potential risks are side effects caused by the methylphenidate therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Age 6-12 years
Recently diagnosed ADHD
Indication for starting with methylphenidate treatment and assignment by the paediatrician to a short methylphenidate/placebo trail.

Exclusion criteria

IQ<80
Treatment with stimulants, melatonin, clonidine, risperidon, benzodiazepines
Prior treatment with melatonin (>0.1 mg)
Contraindications for using methylfenidate
Tourette*s syndrome
Depression
Anxiety disorder
Pervasive developmental disorder
Psychosis
Severe ADHD symptoms (serious behavioural-, attention or learning problems heavily interfering with the child*s live) in which no delay can be made with the initiation of methylphenidate treatment.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	140
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Ritalin
Generic name:	Methylfenidatehydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	11-12-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-07-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-08-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2007-004664-46-NL
CCMO	NL19088.041.07