Are sleep onset problems in adults with ADHD related to a disruption of the circadian rhythm?

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To investigate sleeping disorders in adults with ADHD, especially sleep onset disorders related to the circadian rhythm. Furthermore, the etiology (DNA) as well as possible additional chronobiological and general health variables will be addressed...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON29883

Source
ToetsingOnline

Brief title
Sleep problems in ADHD

Condition

- Other condition
- Cognitive and attention disorders and disturbances

Synonym
sleeping disorders in attention deficit hyperactivity disorder

Health condition

slaapstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: Kenniscentrum ADHD bij volwassenen

Intervention

Keyword: ADHD, adult, circadian rhythm, sleep disorder

Outcome measures

Primary outcome

Between groups with and without sleep onset disorders the following results

will be compared:

- sleep parameters (time to bed, sleep onset SO, sleep latency, wake-up time

WT, get-up time, total sleep duration);

- time of salivary melatonin production onset (Dim Light Melatonin Onset);

- phase angles between DLMO-SO and DLMO-WT;

Secondary outcome

Between groups with and without sleep onset disorders the following results

will be compared:

- melatonin concentration in total amount of overnight urinary production;

- results of questionnaires concerning other sleep disorders, sleep hygiëne,

and additional chronobiological and general health variables;

- non-parametric actometric variables to evaluate (the variability in)

rest-activity patterns.

Study description

Background summary

Are sleep onset problems in adults with ADHD related to a disruption of the circadian rhythm?
Little is known about sleeping disorders in adults with ADHD. A recent study in children has found evidence for a relation between chronic sleep onset insomnia and disruption of the circadian rhythm. Endogenous melatonin production is markedly delayed at night, with an otherwise normal sleeping pattern and quality. This is suggestive for a disturbance of the endogenous circadian pacemaker as found in the delayed sleep phase syndrome or DSPS.

Study objective

To investigate sleeping disorders in adults with ADHD, especially sleep onset disorders related to the circadian rhythm. Furthermore, the etiology (DNA) as well as possible additional chronobiological and general health variables will be addressed.

Study design

In a population of adults with ADHD sleeping disorders, sleep hygiene, and additional chronobiological variables as menstrual cycle, eating pattern and general health will be evaluated using questionnaires. Participants are instructed to complete a sleep log for seven consecutive days and wear a wrist actigraph for 24 h each day to evaluate rest-activity patterns. During one night all overnight urine production will be collected and melatonin concentration assessed. On the following night melatonin concentration in saliva will be assessed by collecting 5 salivary samples hourly by chewing on a cotton plug. To investigate the etiology of sleeping disorders in further studies a salivary sample will be taken for DNA processing. The results of ADHD patients with and without sleep onset disorders will be evaluated.

Study burden and risks

The burden will be minimised for all participants. Patients will receive extensive information on the study rationale and the demands imposed on them. They have to visit our department three times. Completing the questionnaires and sleep log, taking a single salivary sample and wearing the wrist actimeter are minimally demanding. Urine and salivary melatonin measurements can be a burden, salivary measurement somewhat more considering the instructions during the night of collecting salivary samples. The risk of physical or mental disadvantages / complications is negligible.

Contacts

Public

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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 undergoing diagnostic assesment for ADHD at PsyQ Programme Adult ADHD;
- The diagnosis of ADHD is made based on the usual diagnostic procedures:
Semi-structured interview for adult ADHD;
ADHD-Rating Scale (questionnaire on attentiondeficit and hyperactivity);
- Subjects are aged 18 - 55 years;
- Subjects are able to read and understand informed consent forms;
- Subjects are willing and able to answer the research questionnaires and commit to appointments concerning the study.

Exclusion criteria

- Comorbid axis-1 disorders which are clearly present at diagnostic assesment and which can interfere with either the patient's benefit and importance of proper treatment, or the study objectives:
o psychotic disorder;

o major depressive disorder;
o anxiety disorder;
o severe current substance abuse / dependence: more than 2 units of alcohol/day, or in females more than 15 units/wk, in males 21 units/wk; cannabis: more than 1 joint/day. Use of harddrugs is an exclusion criterium;
-Presence of disorders described above will be assessed during the usual diagnostic procedure, and when necessary rigorous psychiatric evaluation will be carried out;
- Use of the following medication within 1 month before participation: stimulants, antidepressants, melatonin, antipsychotics (neuroleptics), clonidine, benzodiazepines (hypnotics), bèta-blockers;
- Suspected dementia, amnestic disorder or other cognitive disorder (DSM-IV);
- Mental retardation;
- Insufficient knowledge of Dutch language;
- Shift work (evening or night) or travelling along > 2 time zones in the last two weeks.

Study design

Design

Study type:	Observational non 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):	01-07-2006
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	13-06-2006

Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (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
CCMO	NL11879.097.06