Intra-individual variability in Dim Light Melatonin Onset in adults with ADHD and delayed sleep phase syndrome

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The main objective of the study is to determine a delayed DLMO in adults with ADHD and delayed sleep phase syndrome compared to a group healthy persons.The second objective is to determine intra-individual variability in the group of participants...

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

Summary

ID

NL-OMON33409

Source
ToetsingOnline

Brief title
DLMO in adults with ADHD and delayed sleep phase syndrome

Condition

- Developmental disorders NEC

Synonym
ADHD

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, delayed sleep phase syndrome, DLMO, variability

Outcome measures

Primary outcome

The DLMO will be compared between adults with ADHD and delayed sleep phase disorder, and healthy volunteers;

- specific comparison of variability of the DLMO in saliva on 5 consecutive days;

- the rhythm of body skin temperature and the melatonin production in the patients and controls;

- results of sleepparameters such as: bed-time, sleep onset, sleep latency, wake-up time, get up time and total sleep duration in hh:mm.

Secondary outcome

- correlation between individual parameters such as: gender, age, weight, length, subtype ADHD, daylength at time of measurement, DLMO, body skin temperature-curve, severity of ADHD, actigraph data;

- actigraph data: among others number of wake bouts, level of activity in least active period, variation in SO/WT-time per day and between different days in research period.

Study description

Background summary

ADHD in adults with delayed sleep phase syndrome (DSPS) has only been investigated to a modest extent, with a lot of possibilities for future

research. In recent publications on adults with ADHD and delayed sleep phase syndrome a relationship was found with a circadian rhythm disorder. It was shown that there was a delayed onset of melatonin production (Dim Light Melatonin Onset or DLMO) in patients compared to controls, a finding that could be consistent with DSPS: a clinical diagnosis of a chronic sleep onset insomnia in which there is a delayed sleep-wake rhythm in subjects with a normal sleep pattern. Unknown is whether there is a intra-individual variablilty in DLMO determined on consecutive nights in subjects with a delayed DLMO, or whether this is constantly delayed. Clinical observation is consistent with the former, although this has not yet been proven. It is important to know if there is variability in the DLMO for both further research and treatment of ADHD and DSPS. If there is intra-individual variability in the DLMO a single measurement of the DLMO will suffice, which is the current procedure in most studies conducted in this area. In this study the DLMO will be measured on five consecutive nights to determine if there is intra-individual variability in the DLMO.

Study objective

The main objective of the study is to determine a delayed DLMO in adults with ADHD and delayed sleep phase syndrome compared to a group healthy persons. The second objective is to determine intra-individual variability in the group of participants with a delayed DLMO.

Study design

Observational research without invasive measurements.

Study burden and risks

Risks are minimal. The burden consists of 6 visits to the clinic. Each visit has a mean duration of 15 minutes.

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

ADHD and delayed sleep phase syndrome has been diagnosed according to regular clinical diagnostic procedures
Age 18-55
Patient/participant is able to read and understand Patient Information
Patient/participant has signed Informed Consent Form
Patient/participant is able and willing to meet follow up appointments for the study

Exclusion criteria

A-Comorbid disorder (Axis I) that is very severe at intake and that may interfere with need of rapid treatment or with the goals of the study:
Psychosis
Depressive disorder
Anxiety disorder
Current substance abuse or substance dependence (alcohol: more than 2 consumptions per day or for women more than 15 consumptions in total per week or for men more than 21 consumptionsin total per week. Cannabis and hard drugs: exclusion per se)
- Use of the following medications within a month prior to participation to the study: stimulants, anti-depressive medication, melatonin, anti-psychotic medication, clonidine, benzodiazepines, beta-blockers
- symptoms of dementia , anamnestic disorders or other cognitive disorders
- mental retardation
- insufficient fluency in the Dutch language

-shift working (evening or night) or traveling in 2 timezones within two weeks prior to participation to the study

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2010
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2009
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	NL27699.097.09

Study results

Date completed:	18-08-2011
Actual enrolment:	24