Effects of melatonin treatment, light therapy, and sleep improvement on psychosocial, cognitive, and behavioural outcomes in children with Delayed Sleep Phase Syndrome and their parents

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39468

Source
ToetsingOnline

Brief title
Melatonin treatment, light therapy, and sleep improvement in children

Condition

- Other condition

Synonym
delayed sleep phase syndrome, sleep onset insomnia

Health condition

slaapstoornissen/circadiane ritmiekstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W,fabrikant Pharma Nord,Pharma Nord

Intervention

Keyword: children, light therapy, melatonin

Outcome measures

Primary outcome

Our primary endpoints are DLMO, sleep onset time, chronic sleep reduction,

behaviour problems, and cognitive functioning.

Secondary outcome

Significant improvements on other variables measured with the questionnaires

(attention problems, inhibitory control, mood, health, functioning at school,

parental sleep, parenting stress, parenting) during and directly after

treatment compared to baseline.

Study description

Background summary

There is much evidence that quality and quantity of sleep is related to psychosocial and behavioural outcomes in children. Although there is a large amount of evidence indicating that sleep restriction leads to impaired functioning, much less evidence is available for the effects of sleep improvement. The current study aims to examine the psychosocial, behavioural, and cognitive effects of sleep improvement in children with insufficient sleep due to Delayed Sleep Phase Syndrome (DSPS).

Study objective

The general aim of the present study is to investigate, in a longitudinal-experimental design, the effects of melatonin treatment and light therapy in children on sleep, health, and various psychosocial, behavioural, and cognitive outcomes. A second aim is to investigate whether improvements in psychosocial, behavioural and cognitive outcomes can be attributed to improved sleep, or to melatonin or light therapy itself. Third, relationships between children*s sleep, functioning, and parenting will be examined.

Study design

The study uses a longitudinal-experimental design (double blind placebo controlled).

Intervention

The study has an experimental design with 3 groups: *melatonin*, *placebo melatonin*, and *light therapy*. Children are randomly assigned to one of the groups. After a baseline period of one week, children receive melatonin treatment, placebo melatonin, or light therapy. After four weeks, children in the placebo condition receive melatonin treatment. Children in the other two groups continue their treatment.

Study burden and risks

Children and parents have to complete questionnaires at three measurement occasions over a period of 17 weeks. In addition, parents have to complete daily sleep diaries for 7 weeks in total, and children have to wear actometers during these periods. Also, at the three measurement occasions children have to complete cognitive tasks on a laptop and at two measurement occasions saliva samples are taken hourly from 19:00-23:00 h to determine DLMO. Parents and children have three site visits in 17 weeks. The risks associated with participation in the study can be considered negligible.

Contacts

Public
Universiteit van Amsterdam

Nieuwe Prinsengracht 130
Amsterdam 1018 VZ
NL
Scientific
Universiteit van Amsterdam

Nieuwe Prinsengracht 130
Amsterdam 1018 VZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- The child is between 7 and 12 years old,
and
- The child has chronic sleep onset problems, which is indicated by:
a. complaint of inability to fall asleep at the desired clock time (Sleep onset later than 20:45 h in children aged 7 years and for older children 15 minutes later per year until and including age 12, and a latency between lights-off time and sleep onset (sleep onset latency) of more than 30 minutes),
b.
the symptoms are present for at least 4 nights a week, for at least 1 month during a regular school period,
and
- Dim Light Melatonin Onset (DLMO, the clock time at which the endogenous melatonin secretion reaches the threshold of 4 pg/ml) later than 19:45 h in children aged 7 years and for older children 15 minutes later per year until and including age 12,
and
- the sleep problems result in problems with daytime functioning . Children should have the following symptoms:
a) sleepiness/tiredness during the day
and at least one of the following:
b) external behaviour problems
c) internal behaviour problems
d) problems with functioning at school.

Exclusion criteria

- pervasive developmental disorder
- chronic pain
- known disturbed hepatic or renal function
- Roter or Dubin-Johnson syndrome
- epilepsy
- use of stimulants, neuroleptics, benzodiazepines, clonidine, antidepressants, hypnotics, or *-blockers within 4 weeks before enrolment
- total IQ <80

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2013
Enrollment:	192
Type:	Actual

Medical products/devices used

Generic name:	bright light
Registration:	No
Product type:	Medicine
Brand name:	Bio-Melatonin 3 mg Placebo
Generic name:	placebo

Product type:	Medicine
Brand name:	Bio-Melatonin 3mg
Generic name:	melatonin

Ethics review

Approved WMO Date:	17-04-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28494
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-000220-18-NL
CCMO	NL38852.018.12
OMON	NL-OMON28494