Effects of melatonin treatment, light therapy, and sleep improvement in children with Delayed Sleep Phase Syndrome

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28494

Source
Nationaal Trial Register

Health condition

Delayed Sleep Phase Disorder, Delayed Sleep Phase Syndrome, DSPD, DSPS, sleep onset insomnia

Sponsors and support

Primary sponsor: University, hospital
Source(s) of monetary or material Support: Pharma Nord

Intervention

Outcome measures

Primary outcome

behaviour problems and cognitive functioning

Secondary outcome

DLMO, sleep onset time and chronic sleep reduction

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).
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 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

After 4 weeks treatment and 12 weeks follow-up

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 for four weeks. A follow-up takes place 12 weeks later.

Contacts

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Eligibility criteria

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 â-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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	192
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-06-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39468
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3884
NTR-old	NTR4045
CCMO	NL38852.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39468

Study results

Summary results
N/A