Long term effects on sleep quality and adverse effects related to (continued) melatonin use since early childhood.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25842

Source
NTR

Brief title
MELDOS LT2

Health condition

CSOI, melatonin, sleep quality

Sponsors and support

Primary sponsor: Faculty of Veterinary Medicine, Pharmacy Department, Utrecht University. In samenwerking met Gelderse Vallei Hospital Ede.
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Current melatonin therapy status ((dis)continuation of therapy, dose, compliance, drug holidays, rebound sleep disturbance after (temporary) cessation of therapy, reason(s) for

cessation or resuming of therapy) and current sleep habits (PSQI and ISI score).

Secondary outcome

Secondary outcomes are chronotype (MEQ score, MSFsc), caffeine consumption, smoking status, use of electronics before bedtime and pubertal development. Furthermore, possible side effects and adverse events will be evaluated.

Study description

Background summary

Background

Melatonin is widely used for pediatric DSPD, in order to adjust children's sleep timing to society's school schedule time standards. Short term melatonin therapy appears to be safe. However, data on the effectiveness and safety of long term melatonin therapy remain scarce. As a result, opinions vary on whether long term melatonin therapy should be implemented so widely in pediatrics. Clearly, more data regarding long term melatonin therapy in pediatrics are needed.

Aims

The primary aim of this study is to evaluate participants' melatonin use and sleep quality. Secondary aims are 1) to assess chronotype and lifestyle factors (e.g. smoking, caffeine intake and use of electronic devices before bedtime) and 2) to investigate occurrence of adverse events and (other) reasons for melatonin cessation.

Methods

All children that completed the melatonin dose finding (Meldos) trial (ISRCTN20033346) (n=69) were eligible to participate in this study. Data collection occured by use of an online questionnaire consisting of validated items assessing subjective sleep quality (PSQI), insomnia severity (ISI) and chronotype (MEQ, MCTQ). Furthermore, the questionnaire evaluated melatonin use, pubertal development and the abovementioned lifestyle factors. Results were compared to data regarding the general Dutch population.

Study design

N/A

Intervention

Data collection will occur through administration of an electronic, retrospective, self-administered questionnaire. Comprising seven parts, the questionnaire assesses demographics, melatonin therapy status, chronotype, sleep quality, pubertal development, smoking behavior, caffeine consumption and use of electronics before bedtime. In total, the questionnaire comprises 101 questions. Depending on their answers, participants come across 46-81 items which take approximately 10-20 minutes to complete.

Contacts

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Eligibility criteria

Inclusion criteria

All participants from the MELDOS trial (ISRCTN20033346)

Exclusion criteria

N/A

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-05-2016
Enrollment:	72
Type:	Unknown

Ethics review

Positive opinion

Date:	04-04-2016
Application type:	First submission

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
NTR-new	NL5574
NTR-old	NTR5930
Other	METC UMC Utrecht : 16/046

Study results