

MELatonin for children with idiopathic chronic sleep onset insomnia, with or without attention deficit hyperkinesia disorder - a DOSe finding trial: a randomised placebo-controlled double-blind parallel group trial

Submission date 13/04/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 13/04/2007	Overall study status Completed	☐ Protocol
Last Edited 08/11/2010	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MELDOS VERSION 2.0

Study information

Scientific Title

Acronym

MELDOS

Study objectives

Chronic sleep disorders are associated with dysfunctioning during the day. Circadian rhythm disorders are a frequently occurring cause of chronic sleep disorders. The time at which the endogenous melatonin production starts to rise plays a key-role in the synchronisation of circadian rhythms. In adults with sleep-wake rhythm disorders and late melatonin onset, exogenous melatonin, when administered at an appropriate time advances both endogenous melatonin onset and sleep-wake rhythm. Pharmacokinetics and side effects of melatonin in children might differ from those in adults. Consequently it is necessary to study the effects of melatonin not only in adults but also in children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethical Committee of the Utrecht University Hospital (Medisch Ethische Toetsingscommissie van het UMC Utrecht) on the 17th June 2003 (ref: 03 /007).

Primary study design

Interventional

Study design

Randomised, placebo controlled, parallel group, double blinded trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Insomnia, Attention Deficit Hyperactivity Disorder (ADHD), sleep disorders

Interventions

The study lasts two weeks. One baseline week, followed by one treatment week with melatonin (commercially available Over The Counter [OTC] product) 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg or placebo treatment.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Melatonin

Primary outcome(s)

1. Actigraphic sleep onset and offset and melatonin onset (defined as the time at which 4 pg/ml melatonin in saliva is reached)
2. Diary lights-off time
3. Sleep latency (latency between lights-off and sleep onset)
4. Sleep onset
5. Sleep duration
6. Sleep-offset and wake up time
7. Behaviour
8. Health status

Actigraphy data (for measurement of primary outcomes 1, 3, 4, 5 and 6) are collected during five days of week one, and five days of week two. Saliva collection (for the measurement of primary outcome 1) is done on day seven of week one and day seven of week two, for measurement of melatonin onset. The diary is recorded during all 14 days of the trial duration (for measurements of primary outcomes 2, 7, 8, and secondary outcome).

At this moment an interim analysis of the actigraphy results of week one (no medication) versus week two (with double blind placebo controlled medication) is ongoing, after 75 patients enrolled.

Key secondary outcome(s)

Possible side effects and adverse events will be evaluated.

Completion date

01/05/2007

Eligibility

Key inclusion criteria

1. At inclusion physical examination, medical history and inclusion/exclusion assessments will be performed. The results of a hypnogram, performed within the past two months, showing a normal sleep architecture has to be known at inclusion
2. The children and their parents have to be motivated to comply the study protocol

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

1. Child-psychiatric or family problems who can explain the sleep onset insomnia
2. Disturbed sleep architecture (hypnogram)
3. Use of Monoamine Oxidase (MAO) inhibitors
4. Children with known disturbed hepatic or renal function
5. Patients with the Roter syndrome
6. Patients with the Dubin-Johnson syndrome
7. Factors or diseases which can, according to the investigator, inhibit participation to the study
8. Medical, environmental, psychiatric or other factors, which can cause sleep onset insomnia during the trial
9. Participation in a study on the efficacy of drugs in the month preceding the inclusion
10. Mental retardation (Intelligence Quotient [IQ] less than 80)
11. Any prior use of melatonin
12. Use of hypnotics, antidepressants or neuroleptics
13. Chronic pain
14. Severe neurological or psychiatric disorder

Date of first enrolment

01/05/2004

Date of final enrolment

01/05/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Utrecht (UMCU)

Ede

Netherlands

6716 RP

Sponsor information

Organisation

Hospital Pharmacy of the Valley of Gelderland (Ziekenhuisapotheek Gelderse Vallei) (The Netherlands)

ROR

<https://ror.org/03862t386>

Funder(s)

Funder type
Industry

Funder Name
Pharma Nord Denmark (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes