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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

Registration date
13/04/2007

Overall study status
Completed

Last Edited
08/11/2010

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.medsys/meldos.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Randomised, placebo controlled, parallel group, double blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
Possible side effects and adverse events will be evaluated.

Overall study start date
01/05/2004

Completion date
01/05/2007

Eligibility

Key inclusion criteria

1. At inclusion physical examination, medial 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

Age group
Child

Sex
Both

Target number of participants
150

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)

Sponsor details
Willy Brandtlaan 10
Ede
Netherlands
6716 RP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03862t386

Funder(s)

Funder type
Industry

Funder Name
Pharma Nord Denmark (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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