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The efficacy and safety of melatonin treatment in children with attention deficit hyperactivity disorder (ADHD) and chronic sleep onset insomnia

Submission date
12/09/2005

Registration date
12/09/2005

Last Edited
17/09/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR69

Study information

Scientific Title

Acronym
MACI

Study objectives
To assess the efficacy and safety of melatonin treatment in children with attention deficit hyperactivity disorder (ADHD) and chronic sleep onset insomnia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, double blind, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Attention deficit hyperactivity disorder, chronic sleep onset insomnia

Interventions
Melatonin (3 mg when body weight less than 40 kg; 6 mg greater than 40 kg) or placebo during 1 month at 19:00 hours.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Melatonin

Primary outcome measure
1. Sleep onset, latency, and total sleep duration as estimated with actigraphy and sleep log
2. Salivary dim light melatonin onset (DLMO).

Measurements take place at baseline, in the third week of a placebo-controlled treatment period.

Secondary outcome measures
1. Computerised measures of sustained attention and response inhibition
2. Severity of ADHD symptoms
3. Quality of life
4. Side effects

Overall study start date
01/11/2001

Completion date
01/11/2005

Eligibility

Key inclusion criteria
1. ADHD
2. Chronic sleep onset insomnia
3. Aged 6 - 12 years, boys/girls
4. Intelligence quotient (IQ) greater than 80

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
110

Key exclusion criteria

1. Epilepsy
2. Chronic pain
3. Renal/hepatic diseases
4. Pervasive developmental disorder
5. Used stimulants, melatotin, neuroleptics, benzodiazepines, clonidin, antidepressants, hypnotics, or beta blockers within four weeks before enrolment

Date of first enrolment
01/11/2001

Date of final enrolment
01/11/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Transvaalstraat 86-c
Amsterdam
Netherlands
1092 HP

Sponsor information

Organisation
University Maastricht (The Netherlands)

Sponsor details
CAPHRI Research Institute
PO Box 616
Maastricht
Netherlands
6200 MD

Sponsor type
University/education

Website
http://www.caphri.nl/

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Research organisation

Funder Name
Foundation De Drie Lichten (The Netherlands)

Funder Name
The Maarten Kapelle Foundation (The Netherlands)

Funder Name
Epilepsy Centre Kempenhaeghe Heeze (The Netherlands)

Funder Name
Hospital Gelderse Vallei Ede (The Netherlands)

Funder Name
Academic Medical Centre (AMC) (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