

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	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2005	Overall study status Completed	☐ Protocol
Last Edited 17/09/2008	Condition category Mental and Behavioural Disorders	☐ 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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

1. Computerised measures of sustained attention and response inhibition
2. Severity of ADHD symptoms

3. Quality of life
4. Side effects

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Years

Upper age limit

12 Years

Sex

All

Key exclusion criteria

1. Epilepsy
2. Chronic pain
3. Renal/hepatic diseases
4. Pervasive developmental disorder
5. Used stimulants, melatonin, neuroleptics, benzodiazepines, clonidine, 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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration