

# The efficacy and safety of melatonin treatment in children with ADHD and chronic sleep onset insomnia.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25413

### Source

NTR

### Brief title

MACI

### Intervention

### Outcome measures

#### Primary outcome

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

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

3. quality of life;

3. side effects.

## Study description

### Background summary

Participating centres:

Hospital Gelderse Vallei, Ede, The Netherlands;  
Epilepsy Centre Kempenhaeghe, Heeze, The Netherlands;  
Reinier de Graaf Gasthuis, Delft, The Netherlands;  
Department of Paediatrics, Rode Kruis Ziekenhuis, Beverwijk, The Netherlands.

### Study objective

N/A

### Study design

N/A

### Intervention

Melatonin (3 mg when body weight <40 kg; 6 mg >40 kg) or placebo during 1 month at 19:00 h.

## Contacts

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### Scientific

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## Eligibility criteria

### Inclusion criteria

1. ADHD,
2. chronic sleep onset insomnia,
3. aged 6-12 yrs,
4. boys/girls,
5. IQ>80.

### 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.

## Study design

### Design

Study type: Interventional  
Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2001
Enrollment:	110
Type:	Actual

## Ethics review

Positive opinion	
Date:	08-08-2005
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	NL42
NTR-old	NTR69
Other	: N/A
ISRCTN	ISRCTN47283236

## Study results

### Summary results

J Am Acad Child Adolesc Psychiatry. 2007 Feb;46(2):233-41.