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# Melatonin treatment for sleep problems in children with autism: a randomised controlled crossover trial

**Submission date**
23/04/2008

**Recruitment status**
No longer recruiting

**Registration date**
19/06/2008

**Overall study status**
Completed

**Last Edited**
27/03/2012

**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

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Barry Wright

**Contact details**
Lime Trees Child
Adolescent & Family Unit
31 Shipton Road
York
United Kingdom
YO30 5RF
+44 (0)1904 726610
barry.wright@nyypct.nhs.uk

## Additional identifiers

## Study information

**Scientific Title**

**Study objectives**

Melatonin will be better than placebo at improving time-to-onset of sleep (sleep latency) and total sleep time.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
York Research Ethics Committee. Date of Approval: 21/01/2004 (ref: 03/12/17)

## Study design
Randomised controlled crossover trial.

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Sleep disorder in autism

## Interventions
This is a crossover trial, with two arms: Melatonin medication vs placebo.

Group 1: One month no medication, 3 months melatonin, 1 month washout, 3 months placebo, 1 month no medication.
Group 2: One month no medication, 3 months placebo, 1 month washout, 3 months melatonin, 1 month no medication.

Melatonin (oral) started at 2 mg 30-40 minutes before planned sleep and increased every 3 nights by 2 mg to a maximum dose of 10 mg, titrating the dose to the response. If good sleep is achieved, the dose is kept at that level.

## Intervention Type
Drug

## Phase
Not Specified

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

## Primary outcome(s)
The following are recorded by the family every day from the beginning of the study for 9 months:
1. Sleep latency (i.e. time to onset of sleep)
2. Number of hours sleep per night (as recorded in daily sleep diaries)

## Key secondary outcome(s))
The following are carried out at baseline and after 4, 8 and 9 months:
1. General Health Questionnaire
2. Sleep Difficulties Questionnaire (Likert scale)

### Completion date
01/11/2008

## Eligibility

### Key inclusion criteria
1. Both male and female children, aged 4-10 years
2. Diagnosis of typical or atypical childhood autism and sleep disorder (as defined by World Health Organization ICD-10 and sub-classified using the International Classification of Sleep Disorders)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
4 years

### Upper age limit
10 years

### Sex
Not Specified

### Key exclusion criteria
1. Children on any other medication including anti-epileptic medication
2. Children previously on melatonin or having any other sleep disorder treatments
3. Any families who do not complete sleep diaries during the one month lead-in period

### Date of first enrolment
01/04/2004

### Date of final enrolment
01/11/2008

## Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**Lime Trees Child**
York
United Kingdom
YO30 5RF

# Sponsor information

**Organisation**
North Yorkshire and York Primary Care Trust (UK)

# Funder(s)

**Funder type**
Government

**Funder Name**
York Innovation Research Fund from the York and Selby Research and Development Committee, Selby and York Primary Care Trust. The Committee is currently represented by the North Yorkshire Research and Development Alliance (http://www.northyorksresearch.nhs.uk) (UK)

**Funder Name**
London Law Trust (UK) (ref: 10/1/04)

# 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 | 01/02/2011 | | Yes | No |