

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

Submission date 23/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/06/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/03/2012	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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)

Secondary outcome measures

The following are carried out at baseline and after 4, 8 and 9 months:

1. General Health Questionnaire
2. Sleep Difficulties Questionnaire (Likert scale)

Overall study start date

01/04/2004

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

Age group

Child

Lower age limit

4 Years

Upper age limit

10 Years

Sex

Not Specified

Target number of participants

32

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**

England

United Kingdom

Study participating centre

Lime Trees Child

York

United Kingdom

YO30 5RF

Sponsor information**Organisation**

North Yorkshire and York Primary Care Trust (UK)

Sponsor details

c/o North Yorkshire Alliance R&D Unit

Learning & Research Centre

York District Hospital

Wigginton Road

York

England

United Kingdom

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+44 (0)1904 726996

research.governance@york.nhs.uk

Sponsor type

Hospital/treatment centre

Website

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

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	01/02/2011		Yes	No