

A blinded randomised cross-over study of the effect of melatonin treatment of sleep disturbances on hypothalamic-pituitary-gonadal axis and leptin in pubertal children

Submission date 12/09/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 13/12/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0263107732

Study information

Scientific Title

A blinded randomised cross-over study of the effect of melatonin treatment of sleep disturbances on hypothalamic-pituitary-gonadal axis and leptin in pubertal children

Study objectives

What is the effect of melatonin on the hypothalamic-pituitary-gonadal axis in pubertal adolescents?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled 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

Nervous System Diseases: Sleep disorders

Interventions

1. Melatonin
2. Placebo

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Gonadotrophin and sex hormone levels
2. Urinary melatonin

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2001

Completion date

01/09/2003

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

20 patients from paediatrics

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2001

Date of final enrolment

01/09/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Paediatrics
London
United Kingdom
W1N 8AA

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Government

Funder Name
University College London Hospitals NHS Trust (UK)

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