

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	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Stopped	☐ Protocol
Last Edited 13/12/2019	Condition category Nervous System Diseases	☐ 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

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

Study type(s)

Treatment

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(s)

1. Gonadotrophin and sex hormone levels
2. Urinary melatonin

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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**

United Kingdom

England

Study participating centre

Department of Paediatrics

London

United Kingdom

W1N 8AA

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

University College London Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration