# 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	Recruitment status	Prospectively registered
12/09/2003	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Stopped	Results
Last Edited	Condition category	Individual participant data
13/12/2019	Nervous System Diseases	Record updated in last year

### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr RM Viner

#### Contact details

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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