

# 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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/12/2019	<b>Condition category</b> 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

Dr RM Viner

### Contact details

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United Kingdom  
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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