ISRCTN31542578 https://doi.org/10.1186/ISRCTN31542578

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr RM Viner

Contact details
Department of Paediatrics
The Middlesex Hospital
Mortimer Street
London
United Kingdom
W1N 8AA
-
a@b.c

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

Primary study design
Interventional

Study design
Randomised controlled trial

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