

# Is melatonin a natural sleep promoter and antidepressant?

<b>Submission date</b> 19/12/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/12/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/05/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
00/05A

# Study information

## Scientific Title

## Study objectives

The purpose and objectives of the research are to determine whether exogenous melatonin will normalise the sleep-wake cycle in depression and improve mood in depression.

## 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)

Hospital

## Study type(s)

Quality of life

## Participant information sheet

## Health condition(s) or problem(s) studied

Neurosciences, psychiatry

## Interventions

Conventional Rx and either melatonin 5 mg nocte or placebo.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Melatonin

## Primary outcome measure

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

05/02/2001

**Completion date**

31/10/2003

## Eligibility

**Key inclusion criteria**

1. Age 18 - 65
2. Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM-IV) diagnosis of major depression (unipolar)
3. Scoring 71 on Beck Depression Inventory (BDI)
4. Waking 2 or more hours than usual

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

72 (36 in each group)

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

05/02/2001

**Date of final enrolment**

31/10/2003

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Royal Free and University College Medical School**  
London  
United Kingdom  
NW3 2PF

## **Sponsor information**

### **Organisation**

The Sir Jules Thorn Charitable Trust (UK)

### **Sponsor details**

24 Manchester Square  
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+44 (0)20 7487 5851  
[julesthorntrust@compuserve.com](mailto:julesthorntrust@compuserve.com)

### **Sponsor type**

Charity

### **Website**

<http://www.julesthorntrust.org.uk/>

### **ROR**

<https://ror.org/03ntprd85>

## **Funder(s)**

### **Funder type**

Charity

### **Funder Name**

The Sir Jules Thorn Charitable 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2010		Yes	No