

Is melatonin a natural sleep promoter and antidepressant?

Submission date 19/12/2002	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 19/12/2002	Overall study status Completed	☐ Protocol
Last Edited 12/05/2011	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

The Sir Jules Thorn Charitable Trust (UK)

Results and Publications

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?
Results article	results	01/05/2010		Yes	No