ISRCTN82912246 https://doi.org/10.1186/ISRCTN82912246

Is melatonin a natural sleep promoter and antidepressant?

Submission date	Recruitment status
19/12/2002	No longer recruiting
Registration date	**Overall study status**
19/12/2002	Completed
Last Edited	**Condition category**
12/05/2011	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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
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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?
Results article	results	01/05/2010		Yes	No