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Melatonin In Acute Mania Investigation (MIAMI-uk)

Submission date	Recruitment status	[X] Prospectively registered
09/04/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/04/2020	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Acute mania or a milder form called hypomania are ways in which bipolar disorder (manic depression) presents. Patients often require hospitalisation and usually require drug treatment with anti-psychotic drugs and mood stabilisers as well as valium-like tranquilisers. The main symptoms include over-activity, racing thoughts, grandiose beliefs and sleep loss. Melatonin is a naturally occurring hormone in the human body which is produced in darkness and suppressed by light. In animal studies it has been shown to inform body tissues about seasonal and light /dark information. In previous studies it caused an improvement in manic symptoms. A further small study of five people showed no effect but was too small a study to answer whether melatonin helps for mania/hypomania. In view of the above it is proposed that melatonin could help as a treatment for acute episodes of mania.

Who can participate?
Manic or hypomanic individuals aged from 18 to 65.

What does the study involve?
Participants will be randomly allocated to take either a melatonin (circadin) tablet or a placebo (dummy) tablet every night 1 hour 30 minutes before sleep for 21 days. Mood and sleep rating scales would be used to assess the progress of the patients on the treatments as well as a special watch which picks up levels of activity and sleep, called an Actiwatch. We will also test if melatonin can improve sleep in this group and reduce overactivity.

What are the possible benefits and risks of participating?
We would expect to see early sleep improvements as well as improvement in other symptoms on a more gradual basis in the group taking melatonin. If successful, it is hoped that early use of melatonin might enable some people to stay out of hospital for their period of relapse and get well sooner.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
July 2008 to December 2009

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Digby Quested
digby.quested@psych.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Digby Quested

Contact details
Warneford Hospital
Headington
Oxford
United Kingdom
OX37JX
+44 (0)1865 223703
digby.quested@psych.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
2008-000281-23

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Melatonin In Acute Mania Investigation (MIAMI-uk): a randomised controlled phase 2 trial

Acronym
MIAMI-uk

Study objectives
Melatonin as a possible treatment for mania.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Oxford REC A, 04/09/2009, ref: 09/H0604/63

Study design
Double-blind randomised controlled phase 2 trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Bipolar disorder

Interventions
Melatonin (circadin) 2 mg tablet orally at night 1 hour 30 min before sleep, or placebo for 21 days.

Intervention Type
Drug

Phase
Phase II

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

Primary outcome measure
Young Mania Rating Scale at baseline, days 4, 7, 14 and 21.

Secondary outcome measures
1. Activity on the Actiwatch to continue for 21 days
2. Quick Inventory of depressive symptoms C16 (Clinician) at baseline, days 4, 7, 14 and 21
3. Quick Inventory of depressive symptoms SR16 (self report) at baseline, days 4, 7, 14 and 21
4. Altman mania rating scale at baseline, days 4, 7, 14 and 21
5. Adverse events. Duration of follow-up: 21 days

6. Leeds Sleep Evaluation Questionnaire (LSEQ), carried out at baseline, day 4, day 7, day 14 and day 21

Overall study start date
01/07/2008

Completion date
29/06/2012

Eligibility

Key inclusion criteria
1. Age limit from 18 to 65, both genders
2. Young Mania Rating Scale >=20
3. In or out-patients meeting the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM4) criteria for bipolar disorder
4. Currently experiencing manic symptoms
5. Capacity to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
90

Total final enrolment
41

Key exclusion criteria
1. Clinically significant substance abuse
2. Comorbid Axis 1 disorders (DSM4)

Date of first enrolment
01/07/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warneford Hospital
Oxford
United Kingdom
OX37JX

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Manor House
John Radcliffe Hospital
Oxford
England
United Kingdom
OX3 9DU

Sponsor type
University/education

Website
http://www.admin.ox.ac.uk/rso/clinical

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name

National Institute for Health Research, Research for Innovation, Speculation and Creativity (RISC) programme (UK)

Results and Publications

Publication and dissemination plan

30/04/2018: Results presented at British Association of Psychopharmacology Conference 2013 https://www.bap.org.uk/pdfs/BAP2013_abstractbook.pdf (page 26)

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?
Basic results			21/04/2020	No	No
HRA research summary			28/06/2023	No	No