ISRCTN47578325 https://doi.org/10.1186/ISRCTN47578325

Evaluation of melatonin therapy on sleep and delirium in intensive care patients

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/09/2008	Nervous System Diseases	

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
N0059122216

Study information

Scientific Title

Study objectives
1. To evaluate the effect of melatonin therapy on the sleep characteristics of intensive care patients.
2. Secondary objectives include studying the incidence of delirium and bispectral index score between patients receiving melatonin or placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Sheffield Research Ethics Committee (UK) on 09/01/03.

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Nervous System Diseases: Sleep disorders

Interventions
Melatonin versus placebo.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure

Sleep and delirium.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/04/2003

Completion date
30/04/2006

Eligibility

Key inclusion criteria
Patients admitted to the adult general intensive care unit with acute respiratory failure requiring mechanical ventilation and then a tracheostomy to assist weaning.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
48

Key exclusion criteria
1. Expected length of stay of less than five further days
2. Previously treated for sleep disturbances
3. Not receiving target enteral feed volume or aspirates greater than 200mls
4. Previous history of convulsions
5. Psychiatric or neurological disease
6. Excessive alcohol consumption (equal to or greater than 50 units per week)
7. Recreational drug use
8. Sleep apnoea
9. Severe heart failure (NYHA III/ IV)
10. Sedative infusions must have been discontinued for more than 24 hours (propofol and alfentanil) or more than 36 hours (morphine and midazolam) with a Sedation Agitation Score (SAS) > 3

Date of first enrolment
01/04/2003

Date of final enrolment
30/04/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
STH NHS Trust
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Sheffield Teaching Hospitals - Central Campus (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	01/05/2008		Yes	No