

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

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 08/09/2008	Condition category Nervous System Diseases	☐ 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
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.

Primary study design

Interventional

Study design

Single centre randomised controlled trial

Study type(s)

Not Specified

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(s)

Sleep and delirium.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

STH NHS Trust

Sheffield

United Kingdom

S10 2JF

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

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