

Melatonin in Intensive Therapy Unit (ITU) 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 14/11/2014	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Bonner

Contact details
Cheriton House
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW
+44 (0)1642 854601

Additional identifiers

Protocol serial number
N0227109607

Study information

Scientific Title

Study objectives

Can melatonin normalise the sleep pattern in patients who have been on ITU for prolonged periods of time?

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)

Treatment

Health condition(s) or problem(s) studied

Nervous System Diseases: Sleep disorders

Interventions

Randomised controlled trial in which melatonin will be given to patients who have ceased to be sedated for their clinical care on ITU, and their physiological and psychological recovery will be recorded. Standard scoring systems are appropriate for this study.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Time to return to a normal hypnogram and perceived normal pattern of sleep.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/08/2003

Eligibility

Key inclusion criteria

ITU patients who have required prolonged sedation (over 24 h) and who will require further ITU management for some days.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2002

Date of final enrolment

31/08/2003

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Cheriton House

Middlesbrough

United Kingdom

TS4 3BW

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

South Tees Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration