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Melatonin in Intensive Therapy Unit (ITU) 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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/11/2014	Nervous System Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/08/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Cheriton House
Middlesbrough
United Kingdom
TS4 3BW

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
South Tees Hospitals NHS 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