

# Melatonin in Intensive Therapy Unit (ITU) patients

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/11/2014	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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