

# Bispectral (BIS) electroencephalogram (EEG) monitored sedation in intensive care unit (ICU) patients. A preliminary randomised controlled trial

<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> 30/04/2018	<b>Condition category</b> Surgery	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0436121370

## **Study information**

### **Scientific Title**

Bispectral (BIS) electroencephalogram (EEG) monitored sedation in intensive care unit (ICU) patients. A preliminary randomised controlled trial

### **Study objectives**

The objective of this study is to investigate whether BIS monitoring has any impact on the sedative requirements in post cardiac surgery ICU patients.

### **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)**

Other

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Sedation in post cardiac surgery

### **Interventions**

Randomised controlled trial. Random allocation to:

1. Standard management
2. Standard management + BIS monitoring

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Specified

**Primary outcome measure**

Comparison of amount of propofol used between the two randomised groups.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/06/2002

**Completion date**

01/06/2003

## **Eligibility**

**Key inclusion criteria**

Postoperative cardiac surgery patients who are expected to have an uneventful postoperative recovery.

**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**

01/06/2002

**Date of final enrolment**

01/06/2003

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Anaesthetics**  
Leeds  
United Kingdom  
LS1 3EX

## **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**  
Not defined

**Funder Name**  
Leeds Teaching Hospitals NHS Trust

## **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