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

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
30/04/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] 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

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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