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An assessment of the efficacy of intrathecal morphine followed by intra-operative remifentanil infusion in the control of early post-operative pain relief in coronary artery bypass surgery.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 13/03/2014	**Condition category** Signs and Symptoms	[ ] 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
N0265006248

Study information

Scientific Title

Study objectives
The aim of this study is to compare the efficacy of intrathecal morphine and intravenous remifentanil against a standard analgesic technique in patients undergoing elective myocardial revascularisation. There are two main questions that it aims to answer:
1. Does this method provide a smooth, reliable, and pain-free recovery after surgery?
2. Is there any difference in pain control, recovery characteristics (e.g. time to resumption of spontaneous respiration, time to reach extubation criteria), or side effect profile?

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Post operative pain

Interventions
Each volunteer will be randomly allocated (using random number tables) to one of two groups:
1. Intrathecal morphine/Remifentanil group
2. Fentanyl/Alfentanil (control) group

After transfer to the ITU the volunteer will remain sedated until they are haemodynamically stable, have a body temperature above 35 degrees Celsius, and are not excessively bleeding. At this point the sedative agent will be stopped and the volunteer will be extubated after specific extubation criteria have been met.

Data will be collected for the pre-, intra-, and post-operative periods.

One of the investigators will remain with the volunteer from the time of ITU admission to the end of the study period. He/she will be responsible for all data collection and will oversee the analgesic management.

The volunteer may request to withdraw from the study at any time. The investigator will withdraw the volunteer from the study if:
1. A critical incident occurs
2. There are peri-operative complications e.g. myocardial dysfunction requiring inotropic support
3. There is excessive post-operative bleeding

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
intrathecal morphine, intravenous remifentanil

Primary outcome measure
To compare the efficacy of intrathecal morphine and intravenous remifentanil against a standard analgesic technique in patients undergoing elective myocardial revascularisation.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2004

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Patients with preserved myocardial function undergoing elective myocardial revascularisation having given written informed consent.

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
01/09/2004

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anaesthetics
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham 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