

# 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.

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/03/2014	<b>Condition category</b> Signs and Symptoms	<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

**Protocol serial number**  
N0265006248

## Study information

## Scientific Title

### Study objectives

The aim of this study is to compare the efficacy of intrathecal morphine and intravenous remifentanyl 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

### Study type(s)

Not Specified

### 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/Remifentanyl group
2. Fentanyl/Alfentanyl (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(s)**

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

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/09/2004

**Date of final enrolment**

01/01/2007

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Anaesthetics**

Birmingham

United Kingdom

B15 2TH

## **Sponsor information**

**Organisation**

Department of Health

## **Funder(s)**

**Funder type**

Government

**Funder Name**

University Hospital Birmingham NHS Trust (UK)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration