

Sedation using sevoflurane during spinal anaesthesia.

Submission date 12/09/2003	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 18/11/2009	Condition category Surgery	☐ 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

Protocol serial number
N0287042181

Study information

Scientific Title

Sedation using sevoflurane during spinal anaesthesia. A single centre, double blind, randomised, placebo controlled study

Study objectives

Sedation using sevoflurane during spinal anaesthesia

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised double blind placebo controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgery: Spinal anaesthesia

Interventions

We aim to compare two groups of patients undergoing spinal anaesthesia. Both groups will receive identical spinal anaesthesia. In addition, one group will receive an inhalational anaesthetic, sevoflurane, as a sedative agent. The second group (control group) will not receive additional sedation.

The patients will be visited before the operation and the technique explained to them. Two anaesthetists will be present during the procedure (anaesthetist A and anaesthetist B). In the anaesthetic room an intravenous cannula will be inserted and a spinal block performed using a 25 gauge needle and 0.5% hyperbaric bupivacaine.

Five patients will be randomly allocated into the sevoflurane or placebo (oxygen/air) group (25 in each). All patients will receive 2 l/min oxygen/air mixture from the anaesthetic machine through nasal cannulae. The anaesthetic machine will be covered so that only anaesthetist A will be able to see the sevoflurane vaporiser. He will add a fixed percentage of sevoflurane (at the moment thought to be 1-2%, but may need to be greater) to the fresh gas flow for patients allocated to the sedation group. The vaporiser will remain turned off for the non-sedation group.

Anaesthetist B will be responsible for assessing levels of sedation at all points during the anaesthetic and recovery phase. This will involve several well recognised psychomotor tests, including the Ramsay Sedation Scale, Trieger's adaptation of the Bender Motor Gestalt Test, and also a tapping test and ball bearing test as used by previous investigators including Short and Galletly. Before anaesthesia, Anaesthetist B will explain the test to the patient. The patient will be visited three times after the operation. First on the recovery ward, and later on the main

ward at 4 h and 24 h after the operation. During these visits, the Trieger, tapping and ball bearing tests will be repeated and the patient will be asked to give a satisfaction rating based on a 10-cm visual analogue scale.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sevoflurane

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

20/05/2003

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility**Key inclusion criteria**

27 (ACT)(COMP)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

21/05/1999

Date of final enrolment

20/05/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Box 17

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Other

Funder Name

Cambridge Consortium - Addenbrookes (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration