ISRCTN36581428 https://doi.org/10.1186/ISRCTN36581428

Sedation using sevoflurane during spinal anaesthesia.

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/11/2009	Surgery	[ ] 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
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

Study design
Randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
21/05/1999

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
27

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
England

United Kingdom

Study participating centre
Box 17
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Other

Funder Name
Cambridge Consortium - Addenbrookes (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