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Sevoflurane-remifentanyl versus propofol-remifentanyl in surgery exceeding 4 hours

Submission date 08/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 11/11/2005	**Overall study status** Stopped	
Last Edited 04/08/2010	**Condition category** Surgery	

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
02/138

Study information

Scientific Title

Acronym
SEVO

Study objectives
No difference between the two types of anaesthetics in patient haemodynamic or wake up characteristics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised active 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
Prolonged surgery

Interventions
Please note that as of 04/08/10 the status of this trial has been updated to "Stopped". The study was closed on 16/01/09 due to difficulties in patient recruitment. The study did not reach sufficient power for trialists to reach a conclusion based on statistical significance.

The main findings were that in the limited number of subjects studied, there no significant differences between the groups in either the primary or secondary objectives. However, it was evident that both techniques can be used effectively for these types of operations.

Randomised into receiving one of two types of anaesthesia.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Sevoflurane, remifentanyl, propofol

Primary outcome measure
Haemodynamic stability

Secondary outcome measures
1. Nausea
2. Vomiting
3. Wake up time

Overall study start date
12/06/2002

Completion date
01/01/2008

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Patients undergoing surgery over 4 hours.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Allergy to sevoflurane or remifentanyl
2. Patient refusal
3. Morbidly obese
4. American Society of Anesthesiologists (ASA) 3 or higher

Date of first enrolment
12/06/2002

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Addenbrooke's Hospital (UK)

Sponsor details
Claudia Rizzini
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/055vbxf86

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories (UK) - Unrestricted educational grant

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