

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

Submission date 08/09/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/11/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/08/2010	Condition category Surgery	<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

Contact name
Dr Basil Matta

Contact details
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

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

R&D Department

Addenbrooke's Hospital

Cambridge

England

United Kingdom

CB2 2QQ

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/055vbx86>

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