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Pharmacokinetics, safety and efficacy of a novel method of sevoflurane delivery

Submission date
08/07/2024

Recruitment status
No longer recruiting

Registration date
18/10/2024

Overall study status
Ongoing

Last Edited
14/10/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Use of sedation, rather than general anaesthesia, has many benefits, including lower rates of postoperative confusion, shorter hospital stay and reduced environmental impact. Effective sedation is a balancing act between awareness and anaesthesia. If too little sedation is given patients may recall intraoperative events and if too much is given patients may require help with their breathing or blood pressure. Although in theory the best way to achieve this balance is to allow patients to sedate themselves by pressing a button, at present sedation is almost exclusively clinician-delivered. This is largely because devices to administer patient-controlled sedation have not been developed. Therefore, this first-in-human clinical investigation of a medical device aims to establish the safety and efficacy of the IDAS mask: a novel device which delivers patient-controlled sevoflurane sedation.

The study will be conducted in an operating theatre suite at Imperial College Healthcare NHS trust and will be funded by Intersurgical Ltd. Up to 18 healthy participants will visit the study centre on one occasion to undertake the study protocol. The study protocol consists of 3 experiments which will investigate the capacity of the IDAS mask to deliver safe and effective patient-controlled sevoflurane sedation. The visit duration will be approximately 12 hours.

If successful, this study will be a steppingstone towards larger seminal clinical investigations of the IDAS mask in patient populations and ultimately could facilitate improvements in the way that sedation is delivered.

Who can participate?
18 - 50 year old participants of any gender and of generally good health

What does the study involve?
You will attend the Theatres and Anaesthetics department at St Mary’s Hospital, Paddington on one occasion. During your visit you will take part in 3 experiments. Each experiment will take between 1 and 2 hours to complete. In total, the visit last approximately 12 hours. Before you participate you will have two screening videocalls, and an anaesthetic preassessment from an anaesthetist and an anaesthetic nurse to ensure that it is safe for you to participate. This will include taking your medical history, examining your mouth and neck, measuring your

physiological observations (oxygen level, breathing rate, heart rate, blood pressure), weight and height, recording an electrocardiogram (ECG), and a pregnancy test (if applicable). Progress to participation is contingent on you successfully completing this screening process.

All experiments will take place in an operating theatre suite. During the experiments you will sit on a theatre trolley and will be required to wear a hospital gown. Before the first experiment an anaesthetist will insert a small needle into a vein in your arm which will be used deliver fluid and other standard drugs as required to ensure your safety during the experiment. During all experiments we will place the IDAS mask over your nose and mouth and we will attach the IDAS mask handpiece to your dominant hand with Velcro straps. We will also place an oxygen sensor on your finger, a blood pressure monitor on your arm, and some stickers on your chest to measure your heart rate.

During the first experiment we will deliver an increasing dose of sevoflurane through the IDAS mask. At regular intervals we will ask you to press the button in the IDAS mask handpiece as quickly as possible when you see the lights in the IDAS mask flash. During the second and third experiments we will attach stickers on your abdomen and your back which we will use to deliver Electrical Muscle Stimulation (EMS). EMS causes harmless, but moderate-severely painful cramps in your stomach muscles. During experiment 2 we will cause up to 6 cramps, each of which will last approximately 1 minute. During experiment 3 we will cause 1 cramp which will last approximately 10 minutes. During both experiment 2 and experiment 3 we will ask you to press the button in the IDAS mask handpiece in order to alleviate the pain of the EMS. It is likely that during each experiment you will fall asleep and will have some memory loss.

Between experiments we will give you time to completely recover from the previous experiment. After each experiment, once you are fully awake, we will ask you questions about what you remember of the experiment. Approximately two hours after completing experiment 3 you will be ready to go home. You will not need to stay in hospital overnight.

What are the possible benefits and risks of participating?
Disadvantages and risks:
Sevoflurane is one of the most commonly used anaesthetic medications worldwide. It has been in use since 1990 and is considered a very safe medication. The predictable side effects of the use of sevoflurane relate to its anaesthetic properties: you will be given amounts of the drug that will produce anaesthesia, which can be associated with slowing of your breathing, obstruction of the airway and lowering your blood pressure. Therefore, to ensure your safety, the experiment will take place in a fully equipped operating theatre suite, and you will be closely monitored at all times by an anaesthetist with expertise in managing these predictable side effects. Unpredictable or unanticipated side effects may occur but are rare, transient and easily treatable, and include nausea, vomiting and shaking. Should the principal investigator have any concerns relating to your safe involvement in the study, your participation may be immediately terminated. When sevoflurane is administered to healthy participants, the risk of any serious complication is less than 1 in 10,000. Extremely rarely (less than 1 in 100,000) patients can have a serious reaction to sevoflurane called malignant hyperthermia. This is an inherited condition and so you will not be allowed to participate in this study if you or anyone in your family has had malignant hyperthermia in the past.

It is possible that if the medications in this study are given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy will be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy.
The EMS will be moderate-severely painful in nature. You will control how much sevoflurane you

need in order to control and manage this pain so that you are comfortable. EMS has no lasting effects, and the pain stops immediately once the machine is switched off. However, you may experience some mild muscle stiffness or soreness for a short time following the study. This is similar to the feeling following intense exercise.

The assessment techniques used to test your ability to press a button are safe and non-invasive and there are minimal risks from having these tests performed under strict safety guidelines. You may have some bruising from the intravenous cannula.

Benefits:
The information we get might help us improve the quality of sedation we are able to offer to patients requiring operations and medical procedures.

Where is the study run from?
St Mary's Hospital, Paddington, Part of Imperial College Healthcare Trust London (UK)

When is the study starting and how long is it expected to run for?
October 2023 to April 2026

Who is funding the study?
Intersurgical Ltd (UK)

Who is the main contact?
Andrew Miller, clinicaltrials@intersurgical.co.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
320908

Study information

Scientific Title
Single centre interventional study of a medical device in adults, to evaluate PHArmacokinetics, Safety and Efficacy of a novel method of Sevoflurane delivery

Acronym
PHASES

Study objectives
To examine the safety and efficacy of patient controlled sedation using a novel method of sevoflurane delivery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/10/2024, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 1224 558458; gram.nosres@nhs.scot), ref: 24/NS/0102

Primary study design
Interventional

Study design
Single centre interventional study

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Sedation and analgesia in adults

Interventions
Single centre interventional study of a medical device. Each participant will undertake three experiments on a single visit:
Experiment 1: the dose-response relationship of investigator-delivered in-mask vaporisation sevoflurane sedation.
Experiment 2: wash-in and wash-out times of participant-controlled in-mask vaporisation sevoflurane sedation during electrical muscle stimulation (EMS)
Experiment 3: maintenance of participant-controlled in-mask vaporisation sevoflurane sedation during EMS

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Prototype IDAS Mask (IDAS PHASES), sevoflurane

Primary outcome(s)
1. Sevoflurane flow rate is measured using device data during the test
2. Participant respiratory pressure in the mask is measured using device data during the test
3. Participant button presses are measured using device data during the test
4. Capnography and pulse oximetry are measured using capnography and pulse oximetry devices during the test
5. Sevoflurane concentration in the mask is measured using device data during the test
6. Room levels of sevoflurane are measured using environmental sensors during the test
7. Participant VAS scores are measured using Visual Analog Scale (VAS) during the test
8. Participant RASS scores are measured using Richmond Agitation-Sedation Scale (RASS) during the test
9. EMS stimulation levels are measured using EMS device data during the test
10. Response times to stimuli are measured using reaction time tests during the test
11. Recall is measured using memory stimuli tests at participant discharge at the end of the day

Key secondary outcome(s)
1. Usability assessments measured using observations during and questionnaire after the investigation to log any difficulties using the device
2. Participant feedback measured using questionnaire on discharge after the investigation

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Age 18 to 50 years
2. Weight 50 to 100 kg
3. BMI 18 to 30 kg/m²
4. Negative infection screen

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
All

Key exclusion criteria
1. Any currently active symptomatic medical condition (ASA 3 or 4)
2. Past medical history or family history of malignant hyperthermia
3. Smoker within the last 12 months
4. Alcohol consumption >14 units per week
5. Known or predicted difficult airway
6. Abnormal physiological observations
7. Pregnancy or possibility thereof
8. Current or recent involvement in any pharmacological research studies
9. Lack of fluency in English

Date of first enrolment
01/10/2024

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College Healthcare NHS Trust
St. Marys Hospital
Praed St
Paddington

London
United Kingdom
W2 1NY

Sponsor information

Organisation
Intersurgical Ltd

Funder(s)

Funder type
Industry

Funder Name
Intersurgical Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the commercial nature of the device

IPD sharing plan summary
Not expected to be made available