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Pilot study of a smart in tracheal tube designed to monitor breathing and body functions (iTraXS 1)

Submission date 12/03/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 30/03/2026	**Overall study status** Ongoing	
Last Edited 03/06/2026	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

When people have surgery under general anaesthetic, a breathing tube is used to help them breathe safely. The position of this tube and the pressure of its cuff must be correct to avoid problems such as low oxygen levels, airway injury, or fluid leaking into the lungs. At the moment, breathing tubes do not give direct information about what is happening inside the airway, so doctors must rely on external monitors, which can sometimes be unreliable.

The iTraXS tube is a new breathing tube that contains very small fibre optic sensors. These sensors can measure oxygen levels and blood flow inside the airway and can help check whether the tube has been correctly placed in the windpipe. This study is the first to test the iTraXS tube in real patients during planned surgery. The aim is to find out whether the sensors work well, whether they can help confirm tube position, whether staff can use the device easily, and whether enough patients can be recruited for a future larger study.

Who can participate?

Up to 40 adults aged 18 to 70 years who are having planned surgery that already requires a breathing tube and an arterial line can take part. People with certain medical conditions, such as difficult airways, severe reflux, or pregnancy, cannot join the study for safety reasons.

What does the study involve?

Participants will receive their usual NHS care. The only differences are:

• The standard breathing tube will be replaced with the new iTraXS tube

• A second iTraXS tube will be gently placed in the food pipe (oesophagus) for a short time to take comparison readings

• A few extra blood samples will be taken from the arterial line, which is already in place, so no extra needles are needed

The sensors will collect information during the operation. All data will be stored securely and anonymously. Participants will be reviewed the day after surgery, and their involvement then ends.

What are the possible benefits and risks of participating?
There is no direct medical benefit to participants. However, the results could help improve the safety of breathing tubes and airway monitoring for people having surgery in the future.

The risks are similar to those of standard breathing tubes. These include a sore throat or hoarse voice, and a very small risk of airway irritation or injury. Extra blood samples carry minimal risk as they are taken from a line that is already in place. If the iTraXS tube cannot be placed easily, the anaesthetist will stop and use a standard tube instead. Usual NHS care always comes first.

Where is the study run from?
The study is run from Queens Medical Centre at Nottingham University Hospitals NHS Trust.

When is the study starting and how long is it expected to run for?
The study is expected to begin on 1 May 2026 and will run for 12 months.

Who is funding the study?
The study is funded by the Medical Research Council (UK) MR/Y008642/1.

Who is the main contact?
The Chief Investigator is Dr David Hewson, david.hewson@nottingham.ac.uk

Contact information

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Public, Scientific

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Integrated Research Application System (IRAS)
345946

Central Portfolio Management System (CPMS)
71300

MRC Grant code
MR/Y008642/1

Study information

Scientific Title
Physiological sensing capabilities of a novel IntraTRAcheal multipleXed Sensing tube: a pilot clinical trial with feasibility assessment (iTraXS 1)

Acronym
iTraXS 1

Study objectives
Primary objectives:
1. Accuracy and reliability of oxygen saturation monitoring from the tracheal mucosa compared with arterial blood values.
2. Accuracy of sensor placement detection (tracheal vs oesophageal).
3. Feasibility of undertaking data collection from the iTraXS device when used in patients as part of a clinical trial.
4. Feasibility of recruitment into a clinical trial of the iTraXS device.

Secondary objectives:
1. Accuracy and reliability of oxygen saturation monitoring from the tracheal mucosa compared with peripheral non-invasive oxygen saturations monitoring.
2. Measurement of intra-cuff pressures and capillary refill time at the tube cuff-tracheal mucosa interface.
3. Usability by healthcare staff in a clinical environment.
4. Safety of the iTraXS device (i.e. time to achieve tracheal intubation, number of intubation attempts(max 2 with iTraXS tube), occurance of failed tracheal intubation).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/02/2026, East of England - Cambridge East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; cambridgeeast.rec@hra.nhs.uk), ref: 25/EE/0250

Primary study design
Interventional

Allocation

Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Surgery

Interventions
All participants will undergo an identical trial treatment regime. There are no group-specific allocations or treatments.

All participants will be anaesthetised by anaesthetists who are members of their usual NHS care team. Participants will undergo surgery as part of their usual NHS care. All treating anaesthetists must undergo trial training provided by designated trial trainers who can demonstrate placement of the iTraXS tube. Training by participating anaesthetists will be documented in training logs.

As per routine clinical practice: following pre-oxygenation of the lungs for 3 minutes via non-invasive facemask, induction of general anaesthesia will be performed by target-controlled intravenous infusion of agents of general anaesthesia. The choice and dose of agents will be at the discretion of the treating usual clinical anaesthetist. After administration of a non-depolarising neuromuscular blocking drug (rocuronium 0.5 mg per kg) and confirmation of loss of muscle tone by qualitative neuromuscular monitoring device, visualisation of the glottis will be undertaken using a videolaryngoscope (Glidescope system). The iTraXS tube will then be placed into the trachea instead of a conventional NHS tracheal tube. As per routine practice tube placement will be confirmed with exhaled carbon dioxide monitoring and positive pressure ventilation commenced. Data collection from the tracheal sensors will commence from entry of the tube into the trachea and continue until removal of the tube from the patient at the end of surgery and general anaesthesia.

Following successful tracheal intubation, a second iTraXS device will be placed into the upper oesophagus to obtain oesophageal signals. This device will not be connected to a mechanical ventilator. Data collection will commence from entry of that tube into the oesophagus. After acquisition of data from the oesophagus, this tube will be removed, leaving only the tracheal tube in place for the rest of anaesthesia and surgery.

General anaesthesia and surgery will proceed under the care of the patient’s usual NHS care team according to routine NHS practice. There will be no deviation from NHS care or treatment.

Upon completion of surgery the participant will be woken from general anaesthesia by their usual NHS clinician and the iTraXS device removed (extubated) in the same manner as a standard tracheal tube.

The iTraXS tubes used for tracheal and oesophageal intubation will both be inspected after removal from the trachea and oesophagus respectively, visually assessing for cuff damage, sensor disruption or displacement or fibreoptic cable damage. Following inspection the iTraXS device will be added to routine NHS clinical waste as per normal practice.

Participants will continue their routine perioperative care for surgery. As part of the trial they will undergo a questionnaire on the first postoperative day seeking information on sore throat or injury after tracheal intubation.

Intervention Type
Other

Primary outcome(s)
1. Accuracy and reliability of oxygen saturation monitoring from the tracheal mucosa compared with arterial blood oxygen saturation measured using comparison of arterial blood sample oxygen saturation values with data extracted from the iTraXS device at during tracheal intubation until removal of the tracheal tube at the end of surgery and general anaesthesia

2. Accuracy of sensor placement detection (tracheal versus oesophageal) measured using data extracted from the iTraXS device at placement of tracheal tube and oesophageal device until removal of the oesophageal device and completion of surgery

3. Feasibility of undertaking data collection using the iTraXS device in patients measured using review of iTraXS device data and completeness of trial case report forms at tracheal tube placement to completion of surgery and postoperative data review on day 1

4. Feasibility of recruitment into a clinical trial using the iTraXS device measured using screening logs and time taken to recruit to target at end of study

Key secondary outcome(s)
1. Accuracy and reliability of oxygen saturation monitoring from the tracheal mucosa compared with peripheral non-invasive oxygen saturation measured using comparison of oxygen saturation data extracted from the iTraXS device with arterial blood sample values at during tracheal intubation until removal of the tracheal tube at the end of surgery and general anaesthesia

2. Intra-cuff pressure and capillary refill time at the tube cuff–tracheal mucosa interface measured using data extracted from the iTraXS device at placement of tracheal tube and oesophageal device until removal of the oesophageal device and completion of surgery

3. Usability of the iTraXS device by healthcare staff in a clinical environment measured using feedback from staff involved in the trial at end of study

4. Safety of the iTraXS device, including time to achieve tracheal intubation, number of intubation attempts, and occurrence of failed tracheal intubation measured using case report form data and safety reporting data including adverse events and serious adverse events at throughout the study

Completion date
01/05/2028

Eligibility

Key inclusion criteria
1. Age 18 - 70 years
2. Undergoing elective surgery with planned tracheal intubation and arterial catheterisation as part of routine NHS clinical care
3. Able to provide informed written consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Known or predicted difficult facemask ventilation or tracheal intubation
2. Previous and planned laryngeal, tracheal or oesophageal surgery
3. History of dysphagia or achalasia
4. History of uncontrolled gastro-oesophageal reflux or known hiatus hernia
5. History of pharyngeal pouch
6. Risk of pulmonary aspiration of gastric contents necessitating awake or rapid sequence tracheal intubation
7. Pregnancy

Date of first enrolment
01/08/2026

Date of final enrolment
01/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
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Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request