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Using light-based imaging to check where a feeding tube is placed in the stomach

Submission date
25/04/2025

Recruitment status
Recruiting

Registration date
13/06/2025

Overall study status
Ongoing

Last Edited
13/06/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The placement of feeding tubes (nasogastric tubes or NGTs) is a common medical procedure, but if the tube is misplaced, it can cause serious problems like food entering the lungs, leading to severe complications. Currently, doctors use X-rays to check the tube's position, which can be disruptive and sometimes gives unclear results. We have developed a new portable device that helps doctors place these tubes more accurately and quickly, using a special light-based technology. This device aims to improve patient safety and make the process faster.

Who can participate?
Adults aged 16 to 75 years who can give written consent and are deemed suitable for the study by a clinical team member can participate. There are two groups:
Healthy volunteers in good general health.
Patients who need an NGT as part of their medical care.

What does the study involve?
Participants will have the new device used during the placement of their NGT. The device uses light to help doctors see where the tube is inside the body in real-time. This will be done at the bedside without needing to move to an X-ray room.

What are the possible benefits and risks of participating?
While there is no anticipated benefit to taking part in this study, we hope the information gained from this study will provide evidence for the future development and use of our optical technology which will reduce the complications arising from misplaced NGTs for patients in the future.

The results of this study may be used for the future commercial development of a new medicinal product, treatment or test. Your participation in this study will not entitle you to benefit financially from the commercial development of the product, treatment or test.

This is early-stage development of the technology. That means that this is the first time our optical technology has been used for this purpose on living human participants. However, all the technology used in this study has undergone extensive pre-clinical testing which has

demonstrated their safety for use in humans. The flexible, light emitting fibre we use has already been approved for use in humans.

There are some risks associated with the placement of the NGT itself rather than the use of the flexible light strip. The most common risks related to the placement of NGTs are discomfort, sinusitis, or a nosebleed. These usually resolve when the NGT is removed. Another, more serious complication is aspiration. Aspiration refers to when fluid or stomach contents are inhaled into the lung. This can happen during insertion of the NGT or if the NGT is misplaced into the patient' s lung instead of their stomach. This can cause coughing and wheezing, and in some cases, pneumonia. The risk of aspiration from NGT placement is low, occurring in a very small percentage of procedures, but that includes cases where medication or nutrition is incorrectly administered.' We will not be using the NGT placed in this study to administer anything so the risk of this is reduced even further. In the unlikely event that there are any issues during the procedure, these will be handled as per usual clinical care.

If you take part in this study you may have up to 4 chest x-rays. This will be extra to those that you would have if you did not take part in the trial. This procedure uses ionising radiation to form images of your body. Ionising radiation can cause cell damage that may, after many years, turn cancerous. The dose you will receive by taking part in this study is equivalent to approximately 7 days natural background radiation. This represents a risk of 1 in 500,000. The natural population risk of developing cancer is 1 in 2.

During the course of a chest X-ray we may discover an incidental finding (something that can be seen on the X-ray that is not part of the study). If we have any concerns, we will contact your GP who will follow this up. This is unlikely to occur but is a possibility.

Where is the study run from?
Royal Infirmary of Edinburgh (UK)

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

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
335526

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AC24242

Study information

Scientific Title
Photon Imaging for Nasogastric Tube Location

Acronym

PINGO

Study objectives
The placement of nasogastric feeding tubes (NGTs) is a routine medical procedure (~271,000 NGTs supplied to the NHS annually) which enables patients to receive nutrition/medications. Intrapulmonary administration of NGT feed, pneumothorax and aspiration pneumonia are infrequent but potentially catastrophic side effects of NG tube misplacement.

Current standards of assessing correct NGT placement include chest radiograph and pH testing, but despite clear guidelines, these catastrophic side effects continue to occur. The British Association of Parenteral and Enteral Nutrition (BAPEN) declared in a recent position paper: “There remains a pressing need for an accurate bedside device/technique to augment or replace pH paper and X-ray”.

Minor complications such as discomfort, sinusitis or epistaxis (bleeding from the nose) are resolved with the removal of the NG tube. However, NG tube placement may cause or worsen a perforation in the setting of oesophageal trauma, and if being placed for the administration of medications or nutrition, intragastric placement must be confirmed. If incorrectly placed, introducing medication or tube feeds to the lungs can cause major complications, including death, this can occur even in intubated patients. A recent review found that 2% of placements utilising small bore NG tubes were inadvertently inserted into the respiratory tract.

Studies using pH and X-ray have demonstrated the need for additional placement methods as both these methods can introduce delays. Using pH readings has shown to introduce possible bias dependent upon the readings and treatment regime of the patient. Whereas the use of X-ray includes the use of additional radiation and time constraints

The team have demonstrated the ability to locate the full path of NGTs using this emerging technology and Early Photon Imaging pre- clinically and in human cadavers. The device has been fully risk assessed and is ready for clinical evaluation. The Photon Imaging Device (PID) is intended to provide real-time NGT location feedback to clinicians.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted, Ethics committee name not provided (Address not provided, City not provided, Zip/postal code not provided; Telephone number not provided; a@a), ref: Reference number not provided

Study design
Single centre non-blinded exploratory proof-of-concept medical device study in healthy volunteers and patients conducted in parallel

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

Hospital

Study type(s)
Safety

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of misplacement of nasogastric tubes in patients

Interventions
The PID is a prototype medical device. It utilises an imaging implementation technique known as time-correlated single-photon counting (TCSPC) to provide a healthcare practitioner with guidance in the placement of Nasogastric Tubes (NGTs).

A light-emitting fibre, placed inside a NGT within a patient's body, will emit photons. A tiny fraction of these photons will emerge from the body with a near line-of-sight / direct path. The PID utilises a highly-sensitive detector positioned outwith the patient to differentiate these early arriving photons from those scattered by tissue (and that therefore arrive at the detector later). The PID is able to use these early arriving photons to calculate and subsequently visualise the location of the light source within the patient. This study will assess if the PID can detect the light being emitted in order to be able to confirm placement of NGT tip.

The device will be used in healthy volunteers and in patients who are having a NGT for medical reasons.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
Photon Imaging Device

Primary outcome measure
Sensitivity (of correct NG tube tip detection in the GI tract below the oesophago-gastric junction or not as confirmed by chest x-ray)

Secondary outcome measures
1. Sensitivity (of correct NG tube tip detection in the GI tract below the oesophago-gastric junction or not as confirmed by CXR) in the days after initial NGT placement (patients)
2. Sensitivity (of correct NG tube tip detection in the GI tract below the oesophago-gastric junction or not as confirmed by CXR) in healthy volunteers
3. For repeated visits only. Narrative recording of any barriers to procedure via investigation team debrief. Clinical user to record narrative user acceptability feedback following each patient

procedure
4. SAE rate measured using patient records
5. Median duration of PID procedure
6. Reasons for withdrawal of consent during or following the procedure (if obtained)

Overall study start date
01/01/2023

Completion date
04/01/2026

Eligibility

Key inclusion criteria
All participants inclusion:
1. Adults aged 16 to 75 years inclusive on the day of enrolment
2. Has capacity to provide written, informed consent
3. Deemed suitable for all study procedures by clinical member of the research team
4. Complies with co-enrolment criteria

Healthy volunteers specific inclusion:
1. In good general health

Patient specific inclusion:
1. NG tube required as part of clinical care

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
16 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
75

Key exclusion criteria
Healthy Volunteer Exclusion:
1. Previous intolerance of NG tube insertion
2. Recent mid face trauma
3. Recent nasal surgery
4. Recent pharyngeal surgery

5. Recent laryngeal surgery
6. Currently prescribed medication which causes therapeutic anticoagulation
7. History of bleeding diathesis
8. History of cirrhosis
9. Stigmata of chronic liver disease
10. Known oesophageal varices
11. History of dysphagia
12. Women (of childbearing potential*) who are pregnant, planning to become pregnant or are breastfeeding
13. Currently detained under the Mental Health Act
14. Any clinically significant abnormal finding, disease or disorder which may significantly increase the risk to the volunteer because of participation in the study, affect the ability of the volunteer to participate in the study or impair interpretation of the study data

Patients Exclusion:
1. Women (of childbearing potential*) who are pregnant, planning to become pregnant or are breastfeeding
2. Treated in isolation for infection control purposes
3. Any clinically significant abnormal finding on clinical examination or screening investigations
4. Currently detained under the Mental Health Act

Date of first enrolment
01/06/2025

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Sponsor information

Organisation

The University of Edinburgh & Lothian Health Board ACCORD

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Sponsor type
University/education

Website
https://www.accord.scot/

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A clinical investigation report will be submitted to the Sponsor, MHRA and REC within 1 year of the end of the study. Where acceptable, a published journal article may be submitted as the clinical investigation report.
The Chief Investigator will provide the clinical investigation report to ACCORD, for review, prior

to finalisation. The clinical investigation report may be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.
Summaries of results may also be made available to Investigators for dissemination within their clinics (where appropriate and according to their discretion).
The Chief Investigator and SMGTMG are committed to publishing the results of the closed appendices promptly.

Intention to publish date
01/01/2027

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date