

Diagnostic accuracy of point-of-care enzymatic test for nasogastric tube placement

Submission date 11/05/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/07/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A nasogastric tube (NGT) is a tube used for giving medication and nutrition that is passed into the stomach via the nose. At least 1 million nasogastric tubes (NGT) are used in the UK each year, often for supplementary feeding in patients unable to swallow. These are tubes that are placed from the nose to the stomach to allow liquid feed to be passed directly into the stomach. It is important that these tubes are correctly placed before use as misplacement can lead to serious complications and even death. The current best practice uses pH testing (measuring acidity or alkalinity) to gastric (stomach) aspirates (matter that has been drawn from the body by suction) to ensure correct positioning in the stomach. This has limitations as it is not always possible to collect an aspirate and up to 42% of patients receive medications that reduce acid in the stomach. In these patients, feeding is often delayed as patients have to wait for a repeat aspiration or undergo a chest x-ray. The ideal solution would be a test that was accurate, safe and rapid even in the context of non-acidic gastric aspirates. Gastric lipase is an enzyme produced in the stomach and therefore if present in aspirates from nasogastric tube confirms correct placement. However, gastric lipase is inactivated by acidic stomach contents and therefore is unsuitable as means of determining nasogastric tube position on its own. The aim of this study is to find out whether a combined test for pH and gastric lipase is as accurate as the current best practice technique of a standard pH test.

Who can participate?

Adult patients who need NCT placement as part of their care.

What does the study involve?

As part of normal clinical management, the NG tube is checked before being used for treatment. The current method of confirmation for correct NG tube placement is by aspirating (sucking out) gastric content from the tube and checking the pH level using pH strips. This is a painless process that is done routinely by the nurses. The same aspirate will be used to impregnate the novel lipase/pH test strip. The second phase of the clinical trial involves endotracheal (ET) tube testing. Patients who have ET tubes as part of their routine clinical management will be invited to the trial. Lung fluid is aspirated from the ET tube and tested on the new lipase/pH test strip. This process is to ensure that the novel lipase/pH strip is able to determine incorrect lung placement of NG tubes.

What are the possible benefits and risks of participating?

Participating in the clinical trial is voluntary and patients do not receive payment of any kind. There are no direct benefits for patients participating in the study. The procedures involved are part of routine management and do not affect their care and treatment. However, through their participation, they will be helping in the development of a new generation of pH strips that are safer and easier to use. These new strips have the potential to improve patient care. There are no notable risks to the patients having surgery.

Where is the study run from?

St Mary's Hospital and nine other NHS hospitals in England (UK)

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

October 2016 to July 2018

Who is funding the study?

Innovate UK (UK)

Who is the main contact?

1. Melody Ni

z.ni@imperial.ac.uk

2. Fatima Akbar

f.akbar@imperial.ac.uk

Contact information

Type(s)

Scientific

Contact name

Ms Melody Ni

Contact details

10th Floor QEQM Building

St. Mary's Hospital

South Wharf Road

London

United Kingdom

W2 1NY

+44 (0)20 3312 6532

z.ni@imperial.ac.uk

Type(s)

Public

Contact name

Ms Fatima Akbar

Contact details

10th Floor QEQM Building

St. Mary's Hospital

South Wharf Road
London
United Kingdom
W2 1NY
+44 (0)203 3126532
f.akbar@imperial.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

192968

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 192968

Study information

Scientific Title

A diagnostic accuracy study to evaluate a point-of-care lipase/pH test strip to confirm correct nasogastric tube position

Study objectives

The novel lipase/pH test is better than the standard pH strips used to confirm locations of blindly inserted nasogastric feeding tubes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - Chelsea Research Ethics Committee, 30/09/2016, ref: 16/LO/0998

Study design

Observational cross-sectional multi-centre diagnostic accuracy study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Patients with nasogastric tube in place for purpose of feeding and/or medication

Interventions

The study will be undertaken in two phases:

Phase 1 - Diagnostic accuracy study

The gold standard (reference test) will be chest x-ray if undertaken or if not required the initiation of nasogastric feeding will determine correct placement. Patients who have nasogastric tube inserted for supplementary feeding or medications will be recruited to the study. They will have aspirates taken after initial insertion or before each use of the nasogastric tube for confirmation of correct placement, which is part of the routine management. The gastric aspirate that has been acquired by the ward staff for their routine testing will be utilised by being passed to a member of the research team to be used in the study. Therefore, the results of the study will not influence patient care. The results for both the enzymatic test and pH test will be compared to the reference test and recorded.

Phase 2 - A study to ensure that the test is able to determine incorrect lung placement of nasogastric tubes.

Patients undergoing routine general anaesthesia will be invited to participate. These patients have endotracheal tubes placed as part of their routine management. Techniques including capnography will be used to confirm that these tubes are correctly placed in the lung. These will be aspirated and used with the novel enzymatic test to ensure a negative result in the case of lung intubation.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Impregnated pH strips

Primary outcome(s)

Sensitivity of the index test and the reference tests (standard pH test) under cut-off 5.5 with tube sites confirmed by either patient follow up or chest x-rays when applicable.

Key secondary outcome(s)

1. Percentage unable to aspirate is measured by the number of patients for whom no aspirate is obtained out of the total number of patients for whom the attempts have been made before either successful aspiration or before chest x-rays has to be requested
2. Number of chest radiographs requested is recorded exactly as described, when aspirates and re-attempts both fail

Completion date

31/07/2018

Eligibility

Key inclusion criteria

1. Patients who require the insertion of nasogastric tubes for supplementary enteral feeding as part of their clinical management
2. Aged 18 years old and over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

396

Key exclusion criteria

1. Under the age of 18 years
2. Unable to sign consent
3. Not providing consent - updated 01/02/2019: Patients who lack capacity
4. Prisoners
5. Patients sectioned under the Mental Health Act

Date of first enrolment

14/12/2016

Date of final enrolment

30/04/2018

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

St. Mary's Hospital

Imperial College Healthcare NHS Trust

Praed Street

London

United Kingdom

W2 1NY

Study participating centre

Hereford County Hosiptal

Wye Valley NHS Trust
Union Walk
Hereford
United Kingdom
HR1 2ER

Study participating centre**Maidstone Hospital**

Maidstone and Tunbridge Wells NHS Trust
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre**Medway Maritime Hospital**

Medway NHS Foundation Trust
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Study participating centre**North Devon District Hospital**

North Devon Healthcare NHS Trust
Chichester House
Barnstaple
United Kingdom
EX31 4JB

Study participating centre**Royal Bournemouth Hospital**

The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Study participating centre

Royal Preston Hospital
Lancashire Teaching Hospitals
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Manchester University NHS Foundation Trust
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Royal Hampshire County Hospital
Mailpoint 45
Room 47, E Floor, Butterfield
Romsey Road
Winchester
United Kingdom
SO22 5DG

Sponsor information

Organisation
Imperial College London

ROR
<https://ror.org/041kmwe10>

Funder(s)

Funder type

Government

Funder Name

Innovate UK

Alternative Name(s)

UK Research and Innovation Innovate UK, innovateuk

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/will be available upon request from Melody Ni (z.ni@imperial.ac.uk) and Fatima Akbar (f.akbar@imperial.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/11/2017		Yes	No
Results article	Development and validation	14/12/2021	11/07/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Pre-results	04/11/2017	11/07/2023	Yes	No
Participant information sheet	version v9	23/10/2016	21/06/2017	No	Yes
Participant information sheet	version v8	23/10/2016	21/06/2017	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes