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

Submission date
11/05/2017

Recruitment status
No longer recruiting

Registration date
21/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
192968

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)

Diagnostic

Participant information sheet
See additional files

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Impregnated pH strips

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
27/10/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
145

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
England

United Kingdom

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

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

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Royal Hampshire County Hospital
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Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of the clinical study and the economic analysis that will be carried out based on the trial data and the human factors work package.

Intention to publish date
31/10/2019

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?
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
Results article	results	04/11/2017		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Pre-results	04/11/2017	11/07/2023	Yes	No
Results article	Development and validation	14/12/2021	11/07/2023	Yes	No