

NGPOD pH test Vs pH measurement to assess Nasogastric Tube (NGT) position

Submission date 01/06/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/12/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A nasogastric tube (NGT) is a narrow tube that is passed into the stomach via the nose for nutritional support or removal of stomach contents (aspirate). Use of misplaced NGT was first recognised as a patient safety issue by the National Patient Safety Agency (NPSA) in 2005 (NPSA, 2005) and three further alerts were issued by the NPSA and NHS England between 2011 and 2013. Introducing fluids or medication into the respiratory tract or pleura via a misplaced NGT is considered a Never Event by NHS England. Never Events are considered preventable but the current methods for determining correct placement of NGTs are open to clinical interpretation. The existing British National Patient Safety Agency (NPSA) safety guideline recommends testing the pH of NGT aspirates. Feeding is considered safe if a pH of 5.5 or lower has been observed, otherwise chest X-rays are recommended. Most NGTs placed in the UK are inserted "blind" - i.e. the inserting method does not use a form of visualisation to establish that they are in the correct position prior to use. Current NHSI (NPSA) guidelines recommend that pH testing of aspirate obtained from the NGT is the first-line method of confirmation. This can be a difficult procedure with only about 60% success in obtaining aspirate and, where aspirate is obtained, a variety of human factors can affect the accurate interpretation of the result. Inability to obtain aspirate currently means that patients are then sent for an x-ray to determine the NGT position. NHSI Level 2 Alert July 2016 identified misinterpretation of the x-ray as the root cause of 45% of NGT related Never Events in the preceding 12 months. A new fibreoptic device, NGPOD, gives an unambiguous result as to the pH of the environment at the tip of the NGT. This study aims to compare use of the device with current standard practice to determine if the device is at least as reliable as testing of pH aspirate. The study will also aim to investigate whether a result is obtained more often using the device which would potentially reduce the requirement for x-rays and reduce the risk to patients of repeated exposure.

Who can participate?

Patients aged 18-85 requiring a NGT as part of their treatment

What does the study involve?

The NGPod fibre optic placement confirmation device is used before standard testing with in the first instance pH testing with pH strips of gastric aspirate obtained from the NGT. If aspirate cannot be obtained or the results from the pH test are inconclusive the standard secondary test

of chest x-ray is used to determine the position of the NGT, in line with local guidelines. The results from one or both standard tests are compared to the result from the NGPOD System to determine whether the NGPOD System is at least as accurate as the current standard testing methods.

What are the possible benefits and risks of participating?

No direct positive benefits but the research may lead to a safer and more cost-effective method for NGT placement. Use of the device may lead to a reduction in the requirement for X-rays which would reduce the exposure of patients to x-rays. Possible risks include the additional time required to carry out the NGPod test which will delay nutrition being administered by 20 minutes.

Where is the study run from?

Royal Preston Hospital (UK)

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

June 2018 to March 2020

Who is funding the study?

NGPod Global Ltd (UK)

Who is the main contact?

Rosemary Howell

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

C_FM_001_Protocol

Study information

Scientific Title

Current scientific title as of 10/01/2019:

NGPOD® pH test compared to current NHS Trust practice to determine Nasogastric Tube (NGT) position

Previous scientific title:

NGPOD vs standard pH testing to confirm NGT position

Study objectives

The NGPOD fibre optic medical device is as reliable in establishing the position of an Nasogastric Tube as current standard methods on both initial insertion and repeat testing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/02/2019, North West - Haydock Research Ethics Committee (3rd Floor - Barlow House, 4 Minshull Street

Manchester, M1 3DZ, UK; +44 (0)207 104 8012; nrescommittee.northwest-haydock@nhs.net), REC ref: 19/NW/0019

Study design

Single-center parallel diagnostic study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Nutrition or medication administered via a nasogastric tube

Interventions

The NGPod fibre optic placement confirmation device will be used prior to the current standard method of confirming NGT position.

The methodology is a feasibility/pilot study and doesn't require randomisation. The participants will not be allocated into groups at random but selected simply on their availability and fitting into the required age bracket (18-85).

The study will include adults between the age of 18-85 who require a nasogastric tube as part of their treatment in order to receive hydration/nutrition/medication via the nasogastric tube or who are having the initial insertion of the NGT for other reasons.

The study is to include two cohorts of research participants:

Patients who have had a new nasogastric tube inserted to establish position immediately following insertion (INITIAL INSERTIONS)

Patients receiving ongoing therapy via NGT prior to a new episode of therapy being administered (REPEAT TESTING)

For both groups the NG POD system will be used prior to standard testing with in the first instance pH testing with pH strips of gastric aspirate obtained from the NGT. If aspirate cannot be obtained or the results from the pH test are inconclusive the standard secondary test of chest x-ray will be used to determine the position of the NGT, in line with local guidelines.

The results from one or both standard tests will be compared to the result from the NGPOD System to determine whether the NGPOD System is at least as accurate as the current standard testing methods.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

NGPOD fibre optic medical device

Primary outcome measure

1. Result of NGPod test (Green Tick/Red Cross displayed on the device), recorded in CRF
2. Result of Aspiration pH (pH scale 1-7), recorded in CRF

Secondary outcome measures

1. Result of x-ray (if required) – positive or negative confirmation (Yes/No)
2. Time for NGPod test (minutes and seconds), recorded in CRF
3. Time for Aspiration test (minutes and seconds), recorded in CRF

Overall study start date

01/06/2018

Completion date

19/03/2020

Eligibility

Key inclusion criteria

Current participation inclusion criteria as of 10/01/2019:

Male or female aged over 18 years of age who require a nasogastric tube for nutrition, hydration or medication.

Previous participant inclusion criteria:

Male or female aged 18-85 requiring a nasogastric tube as part of their treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100 unique individuals

Total final enrolment

177

Key exclusion criteria

1. Children under the age of 18
2. Those not requiring a nasogastric tube as part of their treatment

Date of first enrolment

15/09/2018

Date of final enrolment

01/04/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
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Sponsor information

Organisation
NGPod Global

Sponsor details
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
NGPod Global Ltd

Results and Publications

Publication and dissemination plan
The results will be published on the hospital trust website.

Intention to publish date

19/03/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v0.4	19/07/2019	05/10/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		08/12/2022	07/12/2023	Yes	No