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**PaRTICIPANT Information Leaflet**

**(NASOGASTRIC TUBE GROUP)**

**A diagnostic accuracy study of a Point of Care Lipase pH test strip to confirm the correct nasogastric tube position**

IRAS Study Number: 192968

Principal Investigator:

Professor George Hanna PhD FRCS

Professor of Surgical Sciences / Consultant Surgeon

Imperial College, St Mary’s Hospital, London

Co-investigator:

Sophie Doran

Clinical Research Fellow

Imperial College London

 Date: 23/10/2016

You are being invited to take part in a study that will be looking to see if we can check the correct nasogastric tube position (the tube that goes from your nose down into your stomach) using a sample of fluid that will be tested on a strip of special paper that shows us if the tube is in the right place.

This information sheet explains the nature of the research being undertaken and what the process involves. Please take your time to read the following information and discuss with others if you wish. Should you require any further information or have any questions, please ask a member of the research team, one of whom will introduce themselves to you when they ask for your consent to take part in the study. Contact details are also provided at the bottom of this information sheet. Take time to decide whether or not you wish to participate. Thank you for reading this information sheet.

# What is the purpose of the study?

The purpose of this study is to look at the use of a new test to check that your nasogastric tube is in the correct position. This is important as if a nasogastric tube is not in the correct position (when the tip of the tube is not in the stomach) then using it to deliver feed or medications can lead to harm. Currently, the position is checked by measuring the amount of acid in a sample of fluid that is taken from the nasogastric tube. As the stomach produces acid, an acidic sample demonstrates the tube to be in the correct place. If there is uncertainty a chest x-ray is undertaken.

However, this has problems as many patients take medications that reduce the amount of acid in the stomach. Therefore, the samples taken from the tube are not acidic even when the tube is in the correct place. This leads to unnecessary chest x-rays.

Our new test recognises the presence of lipase in the sample. Lipase is a chemical produced in the stomach that helps with the absorption of food. Therefore, the test will give a positive result when the tube is in the stomach even if acid is not present.

This study aims to look at how good our new test is at ensuring that the nasogastric tube is in the correct place by comparing it to the acid test that is currently used. We will also look at whether using the test leads to fewer patients needing an x-ray.

Why have I been invited to participate?

You have been invited to participate because of the nasogastric tube that you have or will have in place as a part of your clinical care.

**Do I have to take part?**

Participation in this research study is entirely voluntary. It is your decision whether you want to take part or not on the study. If you choose to take part, a copy of the participation information sheet will be provided to keep and you will be asked to sign a consent form.

In the event you decide not to continue in the study, you are free to withdraw anytime without providing any reasons and it will not affect the standard of care you receive throughout your treatment.

**What do I have to do?**

We will need to take a sample of fluid from your nasogastric tube. This may be up to once a day during the time that you have the tube in place. This is often carried out anyway as a routine procedure to check the nasogastric tube is in the correct position before using it for feeding or administration of medications. The procedure will involve the nurse attaching a syringe to the end of your nasogastric tube and gently suctioning out a small amount of fluid from your stomach. This is safe and painless.

We also need to request your permission to access your hospital records for the purpose of the research study only, including blood tests, radiology and pathology results. All your hospital records shall be handled with strict confidentiality in accordance with the Data Protection Act 1998.

# How much aspiration fluid from the nasogastric tube is needed to test the pH?

Aspiration of 0.5-1.0 ml (about a teaspoon) of gastric content from the nasogastric tube is needed for the pH test.

**What will happen to the samples?**

All gastric content samples will be discarded immediately after pH test has been performed.

**Where and for how long will study data be stored?**

All study data will be kept anonymously by allocating each participant a participant study number. A key to match participant study number to hospital patient identification number will be kept in a locked document cupboard within a locked university office in the Department of Surgery & Cancer, St Mary’s Hospital, Praed Street, London, W2 1NY. Consent forms will be stored in the same way. This is so that the study data can be linked to participants’ medication use and chest x-rays (when undertaken) if required.

**What are the advantages of participating?**

There will be no direct advantage to participating in the study as your care and treatment will not be affected. The only exception to this would be if the tests we undertake as part of the study suggest that your nasogastric tube may not be in the correct place. If this is the case then we will tell your clinical team so that they may check this before using the tube. Through your participation, you will be contributing to the development of research that may improve future patient care.

**What are the disadvantages of participating?**

There is no real disadvantage of participating as aspiration of fluid from your nasogastric tube is often performed as part of your ongoing care and is a painless safe procedure.

# Will I be contacted again in the future?

You may be asked to provide up to one sample each day that you have your nasogastric tube in place.

The study is planned to continue until the end of 2016. If you would like to see the results of the study when it is completed, we would be happy to send you a summary of the results and details of any publications that have resulted from the study. A member of the research team will ask if you would like this information to be sent to you.

**What if something goes wrong?**

We do not believe that you would be harmed by donating these samples during this study. Your treatment pathway shall remain the same if you choose to participate on not in this research study.

Imperial College London holds insurance policies that apply to this study.  If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault.  This does not affect your legal rights to seek compensation.

If you are harmed due to someone’s negligence, then you may have grounds for a legal action.  Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Sophie Doran Email: s.doran@imperial.ac.uk or Frances Domingo Email: f.domingo@imperial.ac.uk ).  The normal National Health Service complaints mechanisms are also available to you.  If you are still not satisfied with the response you may contact the Imperial AHSC Joint Research Compliance Office (contact details below).

# Will I receive payment for the samples that I donate to the study?

There shall be no payment for any sample provided and you would hand over any interest in the samples provided.

**Who is organising and paying for the study?**

The study is organised by the NIHR Diagnostic Evidence Co-operative London that is based at Imperial College. Innovate UK has paid for the study. The study is being sponsored by Imperial College London.

**Who has reviewed the ethical considerations of the study?**

This study has received ethical approval from the London - Chelsea Research Ethics Committee (Reference 16/LO/0998).

**I have some more questions, who do I contact?**

Please direct any questions, queries or concerns to the co-investigators for this study:

Ms Sophie Doran email: s.doran@imperial.ac.uk

Ms Frances Domingo email: f.domingo@imperial.ac.uk

Alternatively, you can seek impartial advice from the Patient Advice and Liaison Service (PALS), at PALS, Ground Floor QEQM, St Mary’s Hospital, 41 Praed Street, London W2 1NY, Tel: +44(0)2078867777, Fax: +44(0)2078861753

Lastly, the trust R&D provide a third point of contact: Ms Ruth Nicholson AHSC Joint Research Compliance Office, 510B, 5th Floor Lab Block, Charing Cross Hospital, Fulham Palace Road, London, W6 8RF Tel: +44 (0) 203 311 0212 Fax: +44 (0) 203 311 0203 r.nicholson@imperial.ac.uk

*Thank you again for taking time to read this information leaflet. Your participation in this research is most appreciated.*