UNIVERSITY OF CAMBRIDGE

Cambridge University Hospitals NHS
NHS Foundation Trust

Participant Information Leaflet – Healthy volunteer

Study: The metabolic consequences of Gastrointestinal surgery (IRAS 194370)

Version 2
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Project title: The metabolic consequences of gastrointestinal surgery.

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. The patient advice and liaison service (PALS) at Addenbrooke's Hospital can be approached for independent advice about the research information that you have been given. Thank you for reading this information sheet.

PART 1

What is the purpose of this study? It is widely acknowledged that surgery on the gastro-intestinal tract, particularly the stomach and oesophagus (gullet), changes the way the body senses and processes food. While this can prove beneficial, in many cases we find that people suffer problematic symptoms after surgery. These particularly include the "dumping syndrome", whereby a person may feel flushed, faint or even pass out after a meal. We believe that these symptoms are caused by an overactive response of certain cells in the lining of the gut to food. These cells produce chemical signals (hormones) which would normally tell the body how much food has been eaten, and how to deal with it. When too much of one of these hormones is produced, the body can react badly and make someone unwell. This study aims to understand what hormones are altered by surgery, why this happens and how we can reduce the impact of this problem in people who have had surgery.

The same hormones and processes are most likely involved in the development of some forms of diabetes, and we would equally like to investigate whether they can be harnessed into novel treatments for diabetic patients.

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Metabolic Research Laboratories
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What information will be produced by this study? This study aims to produce information on patterns of eating behaviour, how the body senses and utilises food, and how these findings are affected by the function of the cells that line your intestine. We have designed a study with multiple arms and you may not be invited, or wish, to participate in all of them. However, the collated information collected from you and fellow participants over the whole study will greatly expand our understanding of how surgery changes the body's metabolism.

You are being invited to participate as you are a healthy volunteer, and so results from your participation can be used as a comparator for people who have undergone surgery.

Your specific participation may extend to three specific investigations:

- Internet based questionnaires
- Glucose (sugar) tolerance test
- Continuous glucose monitoring

The questionnaire aspect of the study will assess your attitude and behaviours around eating. You will be sent a link and anonymous code to a secure website hosted by the University of Cambridge, where you will be able to complete the questionnaires. This will take up to two hours and can be split over several days.

The glucose tolerance test will involve attending the Clinical Research Facility at Addenbrooke's Hospital for half a day. You will be asked to fast overnight prior to your attendance. We will give you a sugar based drink, and test your breath for markers of the activity of the bacteria in your gut, and your blood for sugar levels, over four hours. We will collect the blood from a small cannula (plastic needle) which we will insert on your arrival, and the breath test will involve blowing into a small bedside machine. We will also take a small amount of blood to check for markers of disease that may alter your response to the sugar test. In total, we will take less than 50ml of blood (4 tablespoons).

The continuous glucose monitor is a small patch that is attached to your arm or abdomen, which records your body's sugar levels every 5-15 minutes. You will be trained in using the device, and asked to wear it for up to two weeks. This will give us clear information on the trends in your body's sugar levels over time, to allow us to compare the results to people who have had surgery.

Why have I been invited? You have been invited because you have expressed an interest in participating in metabolic research at Addenbrooke's Hospital.

Do I have to take part? You are under no obligation to take part in this study. If you are interested, we will describe the study, give you this information sheet and answer any questions you might have. If you decide to take part in the study, we will then ask you to sign a consent form to show you have agreed to take part. Even after you sign the consent form, you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive in the future.

Will this affect my normal medical care? Your normal medical care will not be affected by this study. However, if you are willing, we will inform your GP if you wish to participate.

What do I have to do? A doctor or nurse from the study team will talk to you about your medical history and complete a questionnaire. This questionnaire will provide us with information relevant to our study, such as your height, weight, age and past medical history, as well as a small amount of information about your family, such as whether any of your relatives suffer from certain diseases. All the information in the questionnaire will be kept strictly confidential, and will only be available to the doctors and nurses on the researching team.

You will be asked to sign a consent form to confirm you are happy to take part in this study.

Study requirements

In the paragraphs below, you will find short descriptions of each part of this study. This information sheet is the comprehensive description of the questionnaire part of the study. If you are invited to participate in the glucose tolerance test branch of the study we will provide you with more detailed information in the future.

Questionnaire: This part of the study can be undertaken from home. We will contact you by email with an online link to an eating behaviour questionnaire, and instructions on how to fill it out. This will not take longer than two hours in total and will need to be done on a computer. You will be asked specific questions about how you feel about food, hunger and meal times.

Separate to the questionnaires above, we will ask you to take part in a "real-time" questionnaire study of eating behaviour. Over a two week period, our computer system will contact you by email or text a maximum of six times a day, at random times (only during waking hours), to prompt you to log in and complete a very short questionnaire (which will take under 5 minutes). This is to assess how you think about food while living normally.

If you do not have a computer or internet access, but would still like to participate, please let the study team know and we may be able to arrange for you to attend Addenbrooke's Hospital and use one of the study team's computers.

Glucose tolerance test studies: We may invite you to attend the Clinical Research Facility at Addenbrooke's Hospital for a test designed to work out how your body senses and responds to food. This would involve attending the unit after an overnight fast, taking a sugary drink or standard meal, and having some blood taken over several hours. We would also ask you to blow into the mouthpiece of a device that measures how active the many bacteria in your intestine are during the test.

If at any point during the study you would like to stop taking part, please let the study team know and we will withdraw you from any future contact or investigations. This will not affect your clinical care in any way.

What are the possible disadvantages or risks of taking part? There are no significant risks to registering for the study. The questionnaire is unobtrusive and can be completed in your own home.

The glucose tolerance test study uses standard methods (an oral glucose tolerance test, or standard meal test) that are in widespread use for the diagnosis of diabetes or testing of gut hormones. Occasionally, participants may suffer a low blood sugar during the test, which we would monitor and treat as necessary.

Should you wish to take part in some, but not all of this study, that is fine – we appreciate your help. Please let us know, and if we invite you to take part in a branch of the study that you would rather not be involved with, please just say and we will not contact you further about it.

There is a small risk that while analysing your blood tests, we will detect abnormalities which you were not aware of before the study. This might include, for example, a new diagnosis of diabetes. If this occurs, we will discuss the matter with you in confidence. If you are willing, we would then talk to your GP who can arrange appropriate treatment if required. While this is a risk of participation in the study, it offers you the possibility of having important conditions diagnosed early, which may be of benefit to your long-term health.

What happens if I experience side effects during or after the study? We think it is unlikely that the procedures involved in this study will cause significant side effects. However, it is possible that some participants may experience minor bruising or arm discomfort from the cannula or lightheadedness due to fasting in the gut hormone study. We will ask you to make a note of any side effects that you experience and we will discuss this with you. If you feel the side effects are more severe than expected, you should contact the investigators promptly, who will arrange for you to be reviewed. In the event of severe symptoms, you should contact the investigators as soon as possible – they are available 24 hours a day and will be able to arrange appropriate assessment and treatment. Telephone Mr Geoffrey Roberts on 01223 767176 (9am-5pm only) or 07740 782742 (24 hrs a day).

Are any devices or drugs involved? Yes – if you take part in the glucose tolerance test of continuous glucose monitor arms of this study, we will use devices that are CE marked for the purpose and in widespread clinical use. You will be fully briefed on the use of these devices at the time.

What are the possible benefits of taking part? We cannot promise the study will help you, but the information we obtain from our experiments will help us to find out more about how surgery affects the way the body senses food. This may lead to new understanding and treatments for patients suffering with troubling symptoms after surgery, and contribute to our overall understanding of how the body works.

Will I be paid for my participation in the study?
Reasonable travel expenses and parking costs will be reimbursed.

What happens if I become pregnant during the study? Pregnant women and those who are breast-feeding will not be able to take part in this study. If you are taking part in the study and become pregnant, please inform the investigators promptly. You may be able to complete the rest of the study after your child is born.

What happens when the research study stops? The blood taken for analysis will be stored until the end of the research study. The information will be used to help researchers and doctors understand gastrointestinal diseases better and will hopefully be used to plan new treatment options for these disorders. If you wish, after the study has been completed, the investigators will send you a report explaining the results of the research.

What if there is a problem? Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information of this is given in part 2.

Will my taking part in the study be kept confidential? Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If you have found this information interesting and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What if new information becomes available? We continuously review the latest scientific reports in order to plan useful and worthwhile experiments. If new evidence came to light, we might consider amending our study design. However, if this occurred, we would explain the changes to you and give you the opportunity to withdraw if you wish.

Will video/audio tapes be used? No

What if there is a problem? If you have a concern about any aspect of this study you should ask to speak to the researchers who will do their best to answer your questions (01223 767176). The Addenbrooke's hospital Patient Advice and Liaison Service (PALS) is also available to offer advice or support and to listen to any concerns (01223 216756). If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure (University of Cambridge), details of which can be obtained from the hospital.

Are there any compensation arrangements if something goes wrong? If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism may be available to you. In the event that something does go wrong and you are harmed during the research and that is due to someone's negligence then you may have grounds for legal action for compensation against the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential? All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

Prof Fiona Gribble, Prof Rebecca Fitzgerald, Mr Richard Hardwick, Mr Geoffrey Roberts and the research nurse in their department, will have access to your personal data. We believe that the confidentiality of your personal data is vital. We will discuss this with you before you give consent. The study will meet the requirements of the Data Protection Act and will adhere to the NHS Code of Confidentiality.

These doctors have either honorary or full NHS hospital contracts which have the appropriate confidentially clauses inserted. It is also possible that representatives of the University of Cambridge or Cambridge University Hospitals NHS Foundation Trust may ask to see the study files, to confirm that

the research is being performed to the required high standards. All members of staff are aware of the requirement for strict confidentiality and work to appropriate confidentiality standards.

What will happen to the samples I give? Once the samples have been obtained by the researchers, they will be coded for identification, with only the Chief Investigator or Associate Investigator having access to the codes. Samples will be analysed and stored in a secure place. After the study has been completed, samples will be disposed of in accordance with the best practice for research samples.

Will any genetic tests be done? No

What will happen to the results of the research study? We plan to write scientific papers in medical journals explaining to others what we have learnt from doing these studies. Personal identities will not be revealed in any publications. Fully anonymised results will be made available via the University of Cambridge Data Repository in line with best practice in research.

Can I withdraw from the study if I change my mind? You will be free to withdraw from this study at any stage without explanation and without affecting your current or future treatment. Any samples taken up to the time of withdrawal will be kept and used in the study for the purposes they were taken for.

Who is organising and funding the research? This study is funded by two large grant-awarding bodies called the NIHR and the Wellcome Trust.

Who has reviewed the study? All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity.

Are there any other studies which I could participate in? We are conducting several similar studies related to the hormonal control of appetite, obesity and type 2 diabetes. If you would be interested in participating in further studies, we would be delighted to give you more information.

Local contact for information. Should you wish to discuss any issues related to this study, please use the contact details below:

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Prof Fiona Gribble
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Thank you for taking the time to read this leaflet and taking part in the study. You will be given a copy of this information sheet and a signed consent form to keep.