PARTICIPANT INFORMATION SHEET

Project Title: Non-invasive Assessment of Human Gastrointestinal Motility with Magnetic Resonance Imaging

Name of Supervisors: Dr. Nira Paskaranandavadivel, Prof. Leo Cheng, Dr. Vinod Suresh and Dr. Recep Avci

Name of Student Researchers: Saeed Hosseini (PhD Candidate), Thiwanka Palmada Kankanamalage (PhD Candidate)

Researcher Introduction

Saeed Hosseini and Thiwanka Palmada Kankanamalage are PhD candidates at Auckland Bioengineering Institute, University of Auckland. Their studies are supervised by Dr. Nira Paskaranandavadivel, Prof. Leo Cheng, Dr. Vinod Suresh, and Dr. Recep Avci.

Project description and invitation

MRI scan is a non-invasive technique used to acquire images describing the anatomy inside the human body. This research aims to assess shape and movement of the gastrointestinal (GI) system of a participant by examining MRI images. After scanning, we will develop a numerical model using these images to analyse the effect of the contractions of the stomach and intestine on digestion. We hope these data allow us to develop a healthy subject model and compare it to patients with digestive disorders.
You are invited to take part in our research study. Before you decide whether to take part, we would like you to understand why the research is being done and what it would involve for you. Once you have read this information sheet, a member of our team will go through the information with you and answer any questions you may have.

Participation in the study is voluntary. If you are a colleague or fellow student, your grades or studies or work relationships at the University will not be affected. You should contact your Supervisor or Head of Department if you feel disadvantaged in anyway. If you agree to take part in this study, you are free to withdraw yourself from the study at any time and withdraw data from the study up to 30 days after the MRI scan without having to give a reason, and this will in no way affect your studies/work at the University.

Selection criteria

- Must be between the age of 18-65
- Must pass MRI safety checks
- Have no metallic, magnetic or electric implants in body
- Not pregnant
- Willing to be informed about incidental findings

Requirement

Only those who pass the MRI safety check will be allowed to participate in the study.

MRI scan duration: Between 1 – 2 hours for the scans and preparation and waiting time might be up to 1 hour. The total time required is 2-3 hours.

MRI scan procedure

Prior to having a scan, you will need to complete a safety questionnaire (“MRI Safety and Consent Form”) which will be checked by the radiographer for any contra-indications, or potential reasons why it would not be advisable for you to have a scan.

No detrimental effects or risks are known from MRI scanning. However, it may not be possible, or safe, to have an MRI scan if you have any of the following:

- Cardiac pacemaker or defibrillator
- Retained cardiac pacing wires
- Surgical clips in the brain
- Electronic inner ear implants
- Metal fragments in your eyes
- Electronic stimulators
- Implanted pumps
You will be asked to change into a gown, and remove all metallic objects and jewellery. The scan will usually take place with you lying on your back in a confined space. Lightweight equipment will be placed on top of or around the region being scanned. As the scanner is very noisy whilst the scan is taking place, you will be given headphones to wear. If you wish, you are able to bring a CD of your choice to listen to during the scan.

The scanning process is painless, and free from X-ray exposure. You will be asked to lie in the scanner, and to remain as still as possible to ensure the resulting images are movement free. The sequences vary in length from a few seconds to several minutes. The radiographer will let you know how long each sequence is going to last, and remind you to stay very still. Some of the short scans require you to hold your breath. These "breath holds" last from 10 to 20 seconds, and this will be fully explained at the time of the scan. At all times you are able to communicate with staff throughout the scan, and are supplied with an emergency buzzer. For your comfort, there is light fresh air coming through the scanner.

Project Procedures

A number of scans are required in order to assess movement patterns of the stomach and intestine. You will be asked to consume a liquid or solid meal. We estimate that the scan period will take between 1-2 hours. You must not consume any other meals during the scan period.

Although small, there are some risks (such as hearing harm due to noises, increase in body temperature, etc.) involved with obtaining an MRI scan. In case of an adverse effect from the MRI scan, specialists will be on hand to provide assistance. Ear plugs will be provided to minimise noise from the MRI machine. If you experience claustrophobia we may terminate the study. Audio communication will be maintained throughout the scan period.

The project duration will be 3 years and up to 20 participants will take part in this study.

If you are willing to receive a summary of findings written in non-academic language please fill the related part in the research consent form.

Other Information

- We will record the age, height, and weight of the volunteer.
- A contact number is needed in case of incidental findings.
- Your MRI data will be available to you on request for up to 30 days from the scan date.
- MRI scanning will take place at Centre for Advanced MRI (CAMRI) and you need to fill CAMRI MRI safety and consent form.
- CAMRI will collect your name and NHI number and these data will only be held by CAMRI and not by the researchers.(see “MRI Safety and Consent form”)
- No other personal information will be recorded.
Data storage / retention / destruction / future use

The MRI data will be transferred from the MRI machine to secure server with password protected folders and only the researchers will have access to this storage. The data will be held on server for up to 6 years from the scan date. After this date MRI data will be deleted.

The MRI data will be made available on your request. You have 30 days from the scan date to request a copy of the MRI data.

All the forms and hardcopies will be stored in a safe place apart from the research data and will be destroyed after 6 years.

Research data may be used in journal publications and conference presentations, but you will not be identified.

Right to Withdraw from Participation

You should be fully aware of the risks and the process of the MRI before deciding to take part. If you have any question about the process you can contact any member of the research team. You have the right to withdraw your participation from the study at any time prior to or during the examination session without providing a reason. You have the right to withdraw your data from the research within 30 days from the scan date without providing a reason.

Compensation

Participants will not be financially compensated for their time.

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by The Accident Compensation Corporation (ACC) under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

Anonymity and Confidentiality

If the information you provide is reported / published, this will be done in a way that does not identify you as its source. The data will be labelled with a unique code to di-identify the participants. This unique identifying code will be used to refer to data later in the research.
Incidental Findings

In the event that a condition which is assessed to be a clinical abnormality is detected through performing a scan on you, you will be informed of this and will be advised to consult your general practitioner.

Because the images are not routinely reviewed by a radiologist we are unable to perform diagnostic scans for medical purposes of areas where you have known abnormalities.

Your contact number in the consent form is needed for informing you in case of incidental findings.

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Research Project Funding

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Contact Details and Approval Wording

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For any concerns regarding ethical issues you may contact the Chair, the University of Auckland Human Participants Ethics Committee, at the University of Auckland Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711.  
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Approved by the University of Auckland Human Participants Ethics Committee on 11/4/2019 for three years. Reference Number 022636