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PARTICIPANT INFORMATION SHEET

Project Title: Non-Invasive Imaging and Modelling of Digestion

Researchers: Dr. Nadun Palmada, Prof. Leo Cheng, Dr. Recep Avci and Dr. Nipuni Nagahawatte

Researcher Introduction

All researchers are from the Auckland Bioengineering Institute, University of Auckland.

Project description and invitation

This study will non-invasively image the breakdown of food within the stomach and the contractions of the stomach walls using Magnetic Resonance Imaging (MRI). Additionally, you have the option to take part in the other aspect of this study which involves recording bioelectrical activity on the abdomen. Using the electrical recordings and the data collected from MRI, computer models of the stomach of the subject will be developed to predict the breakdown of food and subsequent emptying. These computer models will help better understand the chemical-mechanical processes occurring within the stomach. The electrical recordings will also allow us to identify key bioelectrical patterns on the skin-surface related with gastric motility.

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. The MRI scans generated from this study are used for research purposes only and not for clinical or medical purposes. 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 of the researchers, we give our assurance that your grades, studies or work relationships at the University will not be affected. Please contact your Head of Department if you feel this assurance has not been met. Your whānau (family) are encouraged to be involved in this study for support and are welcome to attend the scan and ask any questions. If you agree to take part in this study, you are free to withdraw yourself from the study at any time and withdraw all data from the study up to 3 days after the MRI scan without having to give a reason. This will in no way affect your studies/work at the University of Auckland.

Selection criteria

- Must be over the age of 18
- Must pass MRI safety checks
- Have no metallic, magnetic or electric implants in body

- Have had no previous stomach surgeries
- 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. You will be asked to fast for a minimum of 4 hours prior to the MRI scan.

MRI scan duration: A maximum of 2 hours for the scans and preparation and waiting time might be up to 1 hour. The total time required between 1-3 hours.

MRI scan and electrical activity recording 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 metallic, magnetic or electrical implants in your body. Electrical recordings are completely non-invasive and there are no risks for the participants.

If you have experienced any of the following upper gastrointestinal symptoms in the last 2 weeks including discomfort, heartburn, reflux, nausea, pain and/or bloating, you will be asked to complete a short questionnaire (20 questions) to assess the severity of the symptoms you might have experienced.

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.

The scanning process is painless, and free from radiation 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.

If you opted to take part in the bioelectrical activity recording, then this will be performed prior to the MRI scans on a bed outside the MRI machine. Electrical mapping arrays will be placed on the skin in the abdomen region. You will be asked to stay still with shallow breathing for 10 minutes. Two sets of recordings will be performed before and after you eat a meal. You will not feel any pain or discomfort during the recordings.

Project Procedures

A number of scans are required in order to assess movement patterns of the stomach, and to quantify the amount of food breakdown over time. You will be asked to consume a liquid and/or solid meal that will account for your

dietary requirements. 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 and/or headphones will be provided to minimise noise from the MRI machine. If you experience claustrophobia (fear or discomfort from being in a confined space), you may terminate the study at any time. Audio communication will be maintained throughout the scan period.

The project duration will be 3 years and up to 25 participants will take part in this study.

Other Information

- We will record the age, height, and weight of the volunteer.
- If you are on GLP-1 RA therapy we will need to record medication name, dose, treatment duration, and time since the most recent dose.
- 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 either the Centre for Advanced MRI (CAMRI) or one of the Auckland Radiology Group (ARG) clinics. You need to fill either the CAMRI or ARG MRI safety and consent form.
- CAMRI will collect your name and NHI number and this data will only be held by CAMRI and not by the researchers.
- No other personal information will be recorded.

Data storage / retention / destruction / future use

The MRI data will be immediately de-identified by the MRI technician, upon conducting the MRI scan. The de-identified MRI data will be transferred from the MRI machine to a secure server (UoA research storage) that only the researchers of this study will have access to. The data will be held on a server for a minimum of 6 years from the scan date.

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 will be stored in a safe place apart from the research data and will be maintained for a minimum of 6 years.

Research data may be used in journal publications and conference presentations, but you will not be identified. Links to published work by our group which will include possible future publications using the data collected from this study can be found at: https://www.auckland.ac.nz/en/abi/our-research/research-groups-themes/gastrointestinal-system0/publications.html

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 questions 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 3 days from the scan date without providing a reason.

Compensation

You will receive a $50 voucher to acknowledge the time and effort you have contributed towards the study.

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 de-identify the participants. This unique identifying code will be used in place of your name so that the data cannot be linked back to you.

Incidental Findings

While it is not anticipated, there is a possibility that the imaging studies could reveal unexpected findings. Incidental findings will be handled according to the protocols of ARG and CAMRI and if there are any concerns in your images they will be reviewed by a clinician before being referred to your GP. Your GP will then discuss the nature of the incidental findings with you.

Due to the nature of this study, i.e. the MRI scans generated from this study are used for research purposes, we are unable to perform diagnostic scans for medical purposes of areas where you have known abnormalities.

Your email address in the consent form is needed to inform you in case of incidental findings.

Research Project Funding

This research project is a part of University of Auckland project and supported by Riddet Institute, Palmerston North.

Contact Details and Approval Wording

Researchers	
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If you wish to discuss any Māori-specific cultural matters, please feel free to contact Iwi United Engaged through the following page: https://www.iue.net.nz/contact/.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at +64 9 373 7599 ext. 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Approved by the Auckland Health Research Ethics Committee on 06/03/2024 for three years. Reference number AH26704.