

Participant Information Sheet

Control participant version



Study title: *Brain health in atrial fibrillation*

Locality: **Auckland**

Ethics committee ref.: **20CEN30**

Lead investigator: **A/Prof. James P Fisher**

Contact phone number: **09-373 7599 | Ext 86320**

You are invited to take part in this study. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can withdraw from the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Atrial fibrillation is one of the most common forms of an abnormal heart rhythm. The purpose of this study is to determine whether atrial fibrillation affects the function (i.e., health) of the blood vessels of the brain.

The brain has a high metabolic rate and has a number of mechanisms to make sure that its blood flow is closely matched to the activity of the brain cells (called "neurovascular coupling"). The blood vessels in the brain are also very sensitive to carbon dioxide and widen to increase blood flow when the level of carbon dioxide in the blood is elevated (known as "cerebral carbon dioxide reactivity"). Brain health may be determined from assessments of neurovascular coupling and cerebral carbon dioxide reactivity. This project will employ state-of-the-art methods for assessing neurovascular coupling and cerebrovascular carbon dioxide reactivity, along with those of heart function, at the Centre for Advanced Magnetic Resonance Imaging (CAMRI), University of Auckland.

This study is being conducted by A/Prof. James P Fisher (Principal Investigator, University of Auckland), Prof. David Dubowitz (University of Auckland), Dr. Catherine Morgan (University

of Auckland), Prof Alan Barber (University of Auckland and ADHB), Prof Gregory Lip (University of Liverpool, UK) and A/Prof Mark Webster (University of Auckland and ADHB).

This study has been reviewed and approved by the Health and Disability Ethics Committee [20CEN30] on 05/03/2020 for 5 years.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

We are inviting 2 groups of people to participate. The first group are patients with **atrial fibrillation**. The second group of people will have a **normal heart rhythm**. You have been invited to participate because you have **a normal heart rhythm**.

For safety and scientific reasons you are ineligible to participate in this study if you are: younger than 18 years old, are pregnant, are a smoker, have a body mass index <18 (weight in kilograms divided by height in metres squared), have another significant medical condition (e.g., heart failure, lung disease, recent stroke), or if it is not safe for you to have an MRI scan (e.g., due to metal implants). An investigator will carefully check the inclusion/exclusion criteria with you and answer any queries.

Studies will be undertaken at the **Centre for Advanced MRI (CAMRI)** at the **University of Auckland, Park Road, Grafton**. Participation involves one short screening visit (~45 min) and one MRI scan visit (~1 ½ hours). The general procedure of participating is as follows:

Once you have read this form, an investigator will contact you to make sure that your questions have been answered and check that you understand what is involved and the inclusion/exclusion criteria. They will also ask you a series of short questions to check that it is safe for you to have an MRI scan, and if so schedule a screening visit with you.

Screening visit

At the screening visit (~45 min) an investigator will explain again the nature of the procedures, answer any remaining questions and ask you to complete the Consent Form below. You will then be asked to complete a Health Questionnaire and a MRI Safety Screening Form. Then, providing you meet the study inclusion/exclusion criteria, you will be enrolled into the study. Body weight and height will be measured. Blood pressure will be measured using a cuff placed around your upper arm while you are seated quietly. A mask fitting will be completed in preparation for the MRI scan visit. Finally, you will be asked to complete some short cognitive (mental) tasks on an iPad device.

MRI scan visit

The MRI scan visit will last ~1 ½ hours. Prior to the visit the following pre-study stipulations apply:

- No food intake for 2 hours prior to the study.
- No alcohol on the day before the study and the day of the study, prior to MRI.
- No exercise after 8:00pm the evening before the study and no exercise on the day of the study, prior to MRI.
- No medications on the morning of the study. This can be discussed with a study investigator prior to your appointment.
- Please consume your normal quantity of caffeine (e.g., coffee) during the 12 hours prior to MRI.

For the MRI scan you will change into a gown and remove all metallic objects and jewelry. You will then be asked to lie on your back on a bed, and lightweight “coils” will be placed around your head and chest. Because the scanning is noisy you will be given protective earmuffs and/or ear plugs to wear.

We will monitor your heart rate during the scan using wires attached to sticky patches placed on the chest (ECG). You will also be asked to wear a lightweight mask (or mouthpiece with nose clip). You will then be moved into the scanner. You will be asked to remain still so that the images are movement free. You will be able to make contact with the MRI operator via voice or a buzzer at all times, and you can request to come out of the scanner at any time.

In the first part of the scan you will be able to listen to music while we image your brain anatomy. In the next part we will be taking images of the blood flow in the brain as we assess your neurovascular coupling response and your cerebral carbon dioxide sensitivity. Neurovascular coupling will be determined from your brain’s response to viewing a black/white flickering checkerboard pattern for short intervals. Your cerebral carbon dioxide sensitivity will be determined from your brain’s response to you breathing from a bag containing a gas mixture enriched with a small amount of carbon dioxide (5%). This gas will still contain the normal amount of oxygen (21%). Both of these tasks will be completed twice. The session will conclude with a scan of your heart. MRI scan time will total ~75 minutes.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

About MRI: MRI is routinely used for clinical purposes and has no known harmful effects on the human body. For an MRI scan you lie in a short tunnel inside a scanner machine, which produces a strong magnetic field. This is used to image the anatomy and blood flow of the brain and heart.

Benefits:

There are no direct benefits to you from participation in this study or from the scans we make. The research scans are not a substitute for a clinical MRI exam.

Risks and discomforts:

MRI scan: MRI has been used to image millions of people worldwide with no side effects. Although the possibility of long-term effects cannot be ruled out completely, the weight of experience and opinion is against this. However, MRI is unsafe for people who have magnetic metal implants in their body (e.g. pacemaker, permanent hearing aid, screws/plates from an operation etc.). You will be asked to fill out a safety checklist to make sure that this is not the case for you. Although MRI is not known to affect the unborn child, we exclude people who may be pregnant just to be on the safe side. People who are prone to claustrophobia can find lying in the MRI scanner difficult. Therefore, we do not recommend that they participate. Even though you will be given hearing protection, you may find the level of noise uncomfortable, if this is the case, you can ask for the scan to be halted at any time. You will be offered the opportunity to have a short break between scans, when the noise will stop, however we would ask during this time that you remain still and inside the tunnel of the scanner. Very rarely people can find the scanner makes them feel warm or can feel a tickling or twitching sensation. These feelings are transient (i.e., they will go away when the scanning stops) and are harmless. However, if you feel uncomfortable for this or any reason whilst in the scanner you

should let the MRI operator know via the communication system or the buzzer. It is always your right to request that scanning be discontinued and that you be removed from the scanner.

Cerebral carbon dioxide reactivity assessment: This is a widely used approach for the experimental assessment of brain blood vessel function. The gas mixture enriched with carbon dioxide carries the chance of making you feel breathless, light-headed or dizzy (same feeling as if you have quickly climbed a flight of stairs). The risk of this is low, and further minimised by being applied for a short period of time (~4 minutes), but if you do notice any symptoms, they are rapidly reversed (in a few seconds) by breathing normal room air again. If necessary, you will be able to remove the mask (or mouthpiece) at any time to breathe room air. The experimental protocol will be stopped at your request or if the investigator thinks that it is in your best interests.

WHO PAYS FOR THE STUDY?

This study is funded by the Marsden Fund, Royal Society Te Apārangi and is sponsored by the University of Auckland. As a participant in this study you will not incur any costs. You will receive a \$50 voucher at the end of a MRI scan visit to compensate you for your time.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

Detection of Abnormalities: Your MRI scan is for research and is not a medical examination; therefore the images are not routinely reviewed by a radiologist and we are unable to perform diagnostic scans for medical purposes of areas where you have known abnormalities. There is a small possibility that we may incidentally find an abnormality on the scan or from your heart rate recordings that is clinically significant. In the event of this, you will be informed of this and will be advised to consult your general practitioner. If you do not wish to know about this type of finding, please do not participate.

You should be aware that knowledge of incidental findings outlined above could have consequences for you. For instance it could affect your ability to obtain insurance (whether or not you take the matter further), or your ability to work in certain professions.

WHAT ARE MY RIGHTS?

Your participation in this study is entirely voluntary. You are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage. You have the right to access information collected about you as part of the study. You will be informed of any new information related to the study that becomes available during the study that may have an impact on your health. Your identity will be kept strictly confidential and you will not be identified in the publication of the research findings.

WHAT HAPPENS AFTER THE STUDY?

Confidentiality: All information collected about you during the course of the research will be secure. Your name will appear on the attached Consent Form, which will then be coded with a Participant Identification Number. Other study data will then be stored using this Participant Identification Number and not your name. The de-identified study data will be shared with other researchers on the project, including collaborators overseas. Your de-identified data may be used in future studies by other researchers only with the permission of the Lead Investigator, A/Prof Fisher. The full results of the studies being conducted will not be known until after the last participant has been tested and the data analysed (up to three years). The results will be reported in professional publications and meetings but will not be published in a form that identifies individual participants. If you are interested in receiving a summary of the results, please indicate as appropriate on the consent form below.

Data storage, retention, destruction and future use: Electronic data will be stored on a password protected University of Auckland server. The consent forms will be kept for a minimum period of ten years after which they will be securely destroyed. The fully de-identified study data will be kept indefinitely to allow for publication and future re-analysis.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name, position: Dr James P. Fisher, Lead Investigator

Telephone number: 09 373 7599 | Ext 86320

Email: jp.fisher@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@advocacy.org.nz

If you require Māori cultural support please talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324.

If you have any questions or complaints about the study you may contact the Auckland and Waitemata District Health Boards Maori Research Committee or Maori Research Advisor by phoning 09 4868920 ext 3204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdec@moh.govt.nz