

PARTICIPANT INFORMATION SHEET

Feasibility of Transit Time Flow Measurements in The SCORECARD Project

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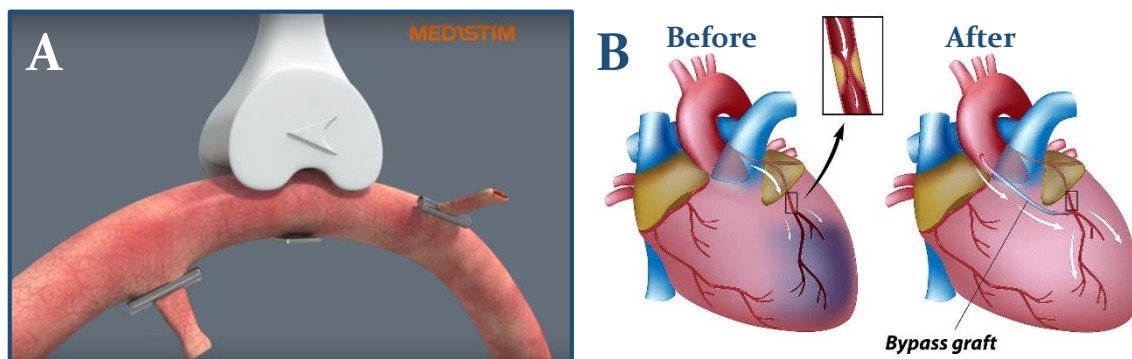
Brief introduction

You have been given this sheet to read because you are going to have a bypass surgery at Auckland Hospital. People have bypass surgery to help go around blockages of the blood vessels that supply blood to the heart. A blockage of these vessels can cause angina, heart attacks or even death.

You are invited to take part in a research study (called The SCORECARD Project). Please take your time to consider this study and to decide whether or not you wish to take part. **Taking part is completely voluntary (your choice). If you decide you do not wish to take part, it will not affect your continuing healthcare in any way.** In this study we will look at how well an ultrasound camera can check the successfulness of the surgery. The research study is also looking to see whether a blood pressure cuff can be used to help the heart during the operation.

Purpose of the study

For people with severe blockages, bypass surgery is the best treatment. This involves connecting blood vessels in such a way that the blockage is ‘bypassed’ and the blood can flow normally. Sometimes, despite our best efforts, the blood vessels do not connect well and this can cause a problem. We want to use a small ultrasound camera (like the one in picture A) to make sure that the connections between blood vessels are working properly. We also want to try and help the heart by using a blood pressure cuff during the operation.



An example of the ultrasound camera is shown in picture A¹. In picture B², a blocked blood vessel shows how poor blood flow to the heart can cause a heart attack. After the bypass operation, you can see the new blood vessel bypassing the blockage. We want to check to make sure that the new blood vessel is working well using the ultrasound camera like the one shown in picture A.

What it involves

If you decide to take part in our study, we will use an ultrasound camera to check whether the blood vessels the surgeon has been working on are working well. We may also place a **second** blood pressure cuff put onto your arm once you are asleep (like the one your doctor puts on your arm when you need your blood pressure checking) that we will inflate during your operation. You won't know whether or not you get given a second blood pressure cuff – this will be randomly decided (like flipping a coin, you will have a 50/50 chance of having a second blood pressure cuff). Everything else about your care

will remain the same. We will collect some information about you and your operation, such as your age, ethnicity and how well you recover. We will also collect information during the operation from the ultrasound camera test. We will collect some identifying information such as your name and hospital number but this will be stored separate from your health information, which will be given a unique study number.

What will happen during the study

If you decide to participate in this study, you will need to complete the consent form at the end of this information sheet, but other than that, you won't have to do anything extra. Your care will be the same as if you decided not to participate, except for two things – we will use an ultrasound camera at the end of your operation to check that the blood vessels in your heart are working properly, and you might have a second blood pressure cuff put on your arm. Both of these things will happen while you are asleep. Remember, if you decide not to take part in this study, it will not affect your continuing healthcare in any way.

Risks and benefits

The ultrasound camera test is now recommended for bypass surgeries by the National Institute for Health and Clinical Excellence, which is an accepted world authority on producing guidelines to help doctors practice at the highest levels. As such, the ultrasound test is very safe and is now being used in many places around the world.

One potential benefit of taking part in this study is that, if the surgeon sees that the operation has not worked to his satisfaction using the ultrasound camera test, then he may double check and revise the operation again. This will all happen in the operating theatre while you are asleep. There are no risks of wearing a second blood pressure cuff. We know that it can help the heart but at the moment we aren't sure if the ultrasound camera test can detect this. This is what we plan to look at in this feasibility study.

Confidentiality

No material that could personally identify you will be used in any reports on this study. All information collected from you will be kept confidential and coded only by a randomly assigned number. The documents that have your name and hospital number on (i.e. your participant consent forms if you decide to participate) will be kept separate from your de-identified study data. All study data will be stored in a secure manner in the Auckland Hospital Support Building.

Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act 2001. ACC cover is not automatic and your case would be assessed by ACC according to the provisions of the Act. If your claim is accepted by ACC, you still might not get 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.

If you have any questions about ACC, contact your nearest ACC office or the investigators.

Independent Advice Services

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact a Health and Disability Advocate.

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

If you have any questions or complaints about the study you may contact the Auckland District Health Board Maori Research Committee or Maori Research Advisor by telephoning 09 486 8920 extension 3204.

This study has received ethical approval from Northern A Health and Disability Ethics Committee (INSERT) and has been registered with the World Health Organisation (World Trial Number INSERT). It has been reviewed by Auckland District Health Board's Research Review Committee ().

Do I have to take part?

Volunteering to take part is absolutely your choice and your care will not be affected in any way if you choose to decline. Having open-heart surgery is stressful enough for patients and their families.

Similarly, if you choose to take part, you could change your mind at any time and let a family member know or your nurse or surgeon and we will withdraw you from the study with no questions asked. These are your rights under the Health and Disability Commissioner's Code of Rights.

Please feel free to ask your surgeon or a SCORECARD Project investigator any questions about the ultrasound camera test or about the blood pressure cuff inflation.

Thank you again for reading this information sheet. We wish you well for your operation and for your stay in hospital.

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² © Cone Health® Medical Group. Image sourced from www.triadctsurgeons.com.