



PARTICIPANT INFORMATION SHEET CLINICAL TRIAL

Tasmanian Study of Echocardiographic detection of Left ventricular dysfunction (TAS-ELF)

Invitation

You are invited to participate in a research study to identify whether an additional investigation designed to identify the early stages of heart muscle damage can avoid heart failure or its consequences in people at risk of heart failure.

The study is being conducted by;

- Prof Tom Marwick, Director of Menzies Research Institute Tasmania, Hobart.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

Heart failure is a common and serious problem in our community. Early stages of heart failure can develop in apparently well people who have risk factors for heart failure. If this process is left unchecked, it can sometimes progress to heart failure. Some new cardiac imaging methods have allowed the early detection of cardiac problems before the patient develops heart failure. We are trying to establish whether this information could guide treatment to protect patients from developing heart failure. Sensitive measures of the heart and an exercise test will be taken in order to measure cardiac status.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you have risk factors that make you more likely than other people to develop heart failure.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the GP or other clinicians caring for you.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

This study is a randomised trial (see definition below) that will be conducted over at least two years. Cardiac measurements will be performed using a painless ultrasound test of the heart. You will be randomised to have either have a standard measurement (ejection fraction, EF) or a new measurement (global longitudinal strain, GLS) from these ultrasound pictures. The aim is to identify whether the information provided by the new test leads to better heart outcomes because your physician is more likely to start you on medications to protect the heart.

We will follow the response of your heart at the beginning and end of these treatment periods by taking ultrasound pictures, an exercise test and blood samples. You will need to attend the clinic on each of these occasions, as well as during regular follow-up.

Definition

'Randomised trial':

Sometimes doctors don't know the best way of treating patients with a particular condition so comparisons need to be made between different treatments. To do this, study participants are put into groups and given different investigations or treatments, and the results are compared to see whether one approach is better. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the doctor nor the study participant can decide which investigation the participant receives.

If you agree to participate in this trial, you will then be asked to undergo the following procedures:

- A screening questionnaire to confirm eligibility, relevant medical history and quality of life.
- Ultrasound pictures of your heart, obtained by pressing an ultrasound probe against the skin. This machine transmits sound waves and collects the reflected waves to make a picture of the reflecting structures.
- We will measure the distance you are able to walk in 6 minutes.
- We will take up to 30 mls (about 2½ table spoons) of blood to test for biochemical markers.

In addition, the researchers would like to have access to your medical record to obtain information relevant to the study.

At the end of the follow-up period, you will then be asked to undergo:

- A repeat questionnaire regarding symptom status and quality of life.
- We will measure the distance you are able to walk in 6 minutes.

We wish to stay in touch with you (by phone or email) for at least 2 years, and have permission to contact you again in the future.

5. 'How is this study being paid for?'

The study is independently supported by the investigators. The Tasmanian Community Fund has partially funded the ultrasound equipment for this study, and the study is also supported by and equipment company (Siemens), who are supporting the application of

new software and providing training. None of the investigators have any duality or conflict of interest. No money is paid directly to individual researchers.

6. 'Are there risks to me in taking part in this study?'

The treatments used to protect the heart when the tests are abnormal are the same, whichever test is used. The classes of drugs we expect to use have been used extensively and are generally safe and well tolerated. Side-effects occur rarely but include low blood pressure (dizziness), gastrointestinal disturbances and skin reactions. If you have a significant symptoms that you think may be due to the agent, please call us and we will discuss stopping the drug.

It is important that women participating in this study are not pregnant and do not become pregnant during the study as the medication we might use may damage an unborn baby. If you are a woman of childbearing age and there is any possibility that you are pregnant, the researchers will need to perform a urine pregnancy test before you start in the study. If necessary, you should use reliable contraception (such as oral or implanted contraception, an IUD or have had a tubal ligation if you are female). If at any time you think you may be pregnant, it is important to let the researchers know immediately.

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. In addition to the risks related to the medication, the other known risks of this study are possibly:

- Discomfort associated with having blood samples taken.
- Discomfort associated with the ultrasound test – which involved pressure against the chest wall.
- Inconvenience associated with visits for the study, or follow-up phone calls.

There may also be risks associated with this trial that are presently unknown or unforeseeable.

7. 'What happens if I suffer injury or complications as a result of the study?'

It is extremely unlikely that you will suffer any injuries or complications as a result of this study. However, if this occurs, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

8. 'Will I benefit from the study?'

This study aims to further medical knowledge and may improve treatment of future cancer patients, however it may not directly benefit you.

9. 'Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not cost you anything. However, you may be reimbursed for parking/travel expenses.

10. 'What will happen to my blood and ultrasound images after the study?'

The images will be stored on a secure computer and blood samples you provide during the study will be stored in a freezer and tested for biochemical markers. The samples will be destroyed 7 years after completion of the study. They will not be used for other research projects, except with your written consent or, under some circumstances, with the approval of a Human Research Ethics Committee at that time.

11. 'How will my confidentiality be protected?'

Of the people treating you, only the investigators and nursing staff involved in the study will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at Menzies Research Institute Tasmania.

12. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to publish the results in peer-reviewed journals and present the findings at scientific conferences. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

13. 'What happens to my treatment when the study is finished?'

You may be able to continue with treatments following completion of this study if your doctor considers them to be of benefit to you. This decision will be made in consultation between you and your treating doctor about the most appropriate treatment for you at that time.

14. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Prof Tom Marwick on 03 6226 7703.

15. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. You will need to quote [*HREC project number H0012445*].

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.**



PARTICIPANT CONSENT FORM

Project Title: **TAsmanian Study of Echocardiographic detection of Left ventricular dysfunction (TAS-ELF)**

I have read and I understand the Participant Information Sheet version 1 dated 01/06/2013.

I freely agree to participate in this project according to the conditions in the Participant Information.

I will be given a copy of the Participant Information Sheet and Consent Form to keep

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

I am aware or I have been informed of the risk of the study medication.

Participant's Name (printed)

Signature

Date

Name of Witness to Participant's Signature (printed)

Signature

Date

Researcher's Name (printed)

Signature

Date

Note: All parties signing the Consent Form must date their own signature.