Biomarkers and Stroke Prevention in Atrial Fibrillation using Electronic Decision Support

Participant information sheet

You are invited to take part in this research because you have, or have had atrial fibrillation.

Atrial fibrillation increases the risk of stroke, heart failure and death. Preventive medications, which include anticoagulants (or blood thinners) and blood pressure medications, are known to reduce these risks. It is sometimes difficult for doctors to decide which medications are best for each person with atrial fibrillation.

PURPOSE OF RESEARCH

Part 1: The first part of the research will evaluate an electronic decision support tool designed to help doctors make the best medication decisions for people with atrial fibrillation.

Part 2: The second part of the research will determine whether a blood test to measure two heart proteins, troponin and B-type natriuretic peptide, is useful to help doctors make the best medication decisions for people with atrial fibrillation.

WHAT WILL MY PARTICIPATION INVOLVE?

Part 1: For the first part of the research your doctor will use an electronic decision support tool to check risks related to your atrial fibrillation and your general health. They will use this information to help choose the best treatments for you. To evaluate this tool we request consent to use de-identified information from your medical records and national data-bases.

Part 2: For the second part of the research your general practice will be randomized either to recommend or not to recommend a blood test to measure heart proteins. We will ask you if you agree to have this blood test.

If your practice is randomized to recommend the blood test, your doctor will ask you again if you wish to have this blood test. The result will be sent to your doctor and included in the electronic decision support tool. Your doctor will then discuss the blood test result with you, and whether any change to your medication may be beneficial. You will be provided with information on any medications which may be recommended.

If your practice is not randomized to recommend the blood test, this will not be offered to you as part of this research. Your doctor will still use the electronic decision support tool, and give you advice on the best medications for your atrial fibrillation.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS?

Medications recommended using the electronic decision support tool are the same as those recommended in usual care. They have each been proven to reduce the risk of stroke, heart attack, heart failure and death, and are commonly taken by patients with atrial fibrillation. Medications can have side effects. If side effects occur you should talk to your doctor about stopping the medication and any alternatives that are available. If you participate in this research some recommendations on your medication may change. However, your doctor decides which medications to prescribe, in consultation with you.

Any additional medical costs related to the study will be paid for by the study (blood tests and additional GP visits).

WHAT ARE MY RIGHTS?

Information from your electronic medical record is used for this research. You have the right to see this information. De-identified electronic data used for this research will be securely stored for 10 years at the Best Practice Advocacy Centre in Dunedin. Study data will only be used for research to improve the care of patients with atrial fibrillation.

Participation in research is voluntary. You can choose not to participate. You can also withdraw at any time without disadvantage. If you do not want to participate in the research to evaluate the blood test for heart proteins, you can still participate in the evaluation of the electronic decision support tool.

If you have the blood test, your blood will be tested to measure the two heart proteins at a clinical laboratory. Blood will not be saved or sent overseas.

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

If you have questions about this research, please first ask your GP or practice nurse.

You can contact the researchers through the B-SAFE Study Co-coordinator, Cardiovascular Research Unit, Auckland City Hospital, Telephone number: 09 307 4949 Extension: 23785, Email: cvregistrytrial@adhb.govt.nz

If you want Māori cultural support please talk to your whānau in the first instance. Alternatively, you may contact He Kamaka Waiora (Māori Health Gains Team) by telephoning the team leader on phone 09 307 8968 or 021 924 032.

The research is being undertaken by heart, stroke and primary care specialists from throughout New Zealand. It is funded by the Health Research Council (HRC) of New Zealand and is being monitored by the HRC Data Safety Monitoring Committee.

The study has been approved by the Regional Health and Disability Ethics Committee; reference number 17/STH/73.

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Participant consent form

Part 1

I give my consent for de-identified information from my medical records to be used for research to evaluate an electronic decision support tool for atrial fibrillation.

Yes No

Part 2

If my general practice is randomized to recommend a blood test to measure heart proteins, I agree to have this blood test. I understand my doctor will inform me of the result, and discuss whether changes to my medication could benefit me.

I also give consent for de-identified information from my medical record to be used for this research.

Yes No

Name _____ Signature_____

Practice name _____

Consent obtained by _____ Date_____