Participant Information Sheet

Multi-Ethnic New Zealand Study of Acute Coronary Syndromes (MENZACS Study)

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Locality: The University of Auckland
(Auckland City Hospital and Middlemore Hospital) and Christchurch Heart Institute

You are invited to take part in this study which is trying to find out how genetics and environmental factors play a part in a person getting heart disease. This study does not involve any new drugs or treatments. Before you decide to participate, it is important for you to understand why this research is being done and what it will involve. Please read this form carefully and discuss it with other people, such as family, whānau, friends, or healthcare providers. If you don’t want to take part, you don’t have to give a reason, and it won’t affect any care you receive. If you do want to take part now, but change your mind later, you can leave the study at any time without giving a reason. If you decide to take part now, you will be asked to sign a consent form which is 2 pages long. You will be given a patient information sheet and consent form to take home.

Thank you for reading this

WHAT IS THE PURPOSE OF THIS STUDY?

We would like to find out more about what can cause heart attacks. A heart attack or angina (chest pain) are common conditions which happen when a blood vessel that supplies blood to a part of the heart becomes narrowed or blocked. Genetics or inherited factors that play a part in heart attacks and angina have not been studied widely in New Zealand. Also, the differences between ethnic groups have not been explored very much. By looking for differences we may be able to discover more about the causes of heart disease. This may lead to treatments for different people, based on their genetics and their environment.

Funding for this study is being provided by the Heart Foundation of New Zealand.

This study has been approved by the Health and Disability Ethics Committee and its reference number is 15/NTB/59.

WHAT WILL THE STUDY INVOLVE FOR YOU?

You have been invited to be involved because you have had a heart attack or angina. To be part of this study we would ask you to:

- Complete a questionnaire that asks about your heart health, family history of heart disease, family background, and information about your diet and exercise, and stress. This will take about 30 minutes to complete. You do not have to answer every question if you do not want to.
• Give a blood sample (about 40 ml) from which we can obtain your DNA, and measure other markers of heart disease risk.
• Have your blood pressure, weight, height and waist measured.

**HOW WILL THE INFORMATION BE STORED?**

The information gathered will be stored in the All New Zealand Acute Coronary Syndrome - Quality Improvement (ANZACS-QI) database and a secure cardiovascular genetics database at the University of Auckland. All participants will have a study number. No information identifying you will be released as part of this research.

Your blood sample will be identified by a code number so that laboratory staff will not know your identity. Your DNA will be stored in secure laboratory facilities identified only by your code number. You may withdraw your sample from the study at any time without explanation and your sample will be destroyed, or returned to you if you wish.

The blood sample will be used to:

- assess markers of heart function that can be measured in the blood such as natriuretic peptides and other circulating markers of heart function
- obtain your DNA, which makes up your body’s genetic code. DNA will be used to look for genes thought to be associated with an increased risk of heart attack and angina.

**WHAT WILL MY BLOOD SAMPLE BE USED FOR?**

Your blood is being collected for research into heart disease. This research will be done at the University of Auckland and at the Christchurch Heart Institute, University of Otago.

The sample you give will be securely stored for the duration of the study, which could be as long as 20 years. Medical testing of samples is always advancing and we may be able to learn more about heart disease by further testing at a later date. Your consent to be involved in this study also includes future testing by the research team for the purpose of finding out more about heart disease.

If you or your whānau/family have any cultural, spiritual or religious beliefs regarding the handling and disposal of human samples please inform the research team and we will ensure that your sample is managed and disposed of accordingly. You can choose whether any sample remaining at the end of the study is disposed of using standard disposal methods or disposed of with, for example, a karakia (blessing).

Some samples may need to be sent overseas for analysis by collaborating investigators or through industry contracts developing similar genetic or circulating biomarker tests. Any blood samples sent to sites outside New Zealand will be labelled with a coded number only. Unused samples will be destroyed by standard disposal (disposal by karakia will not be available in this instance). Only the necessary amount would be sent overseas for specific testing, so it unlikely that there would be any sample left over. You will find a section in the consent form where you can decide if you want your sample to only be used in NZ or if you are happy for it to be sent overseas.

Other researchers may apply to an ethics committee to use the samples and medical history data for research into other genetic diseases in the future. You can be involved in this study and still choose not to have your sample available for other research. You will find an option on the Consent Form where you can say if you consent to your information and blood being used in the future.

**WILL I OR ANYONE ELSE BE GIVEN THE RESULTS OF MY GENETIC ANALYSIS?**

Even when the genes involved in heart disease have been identified, it is still unlikely that we’ll be able to tell people if they are going to have a heart attack because there are also influences from environmental factors.
and lifestyle factors. At this stage it seems unethical and may be misleading to provide individual genetic
data to people before we know how the information should be interpreted, so you will not receive any
individual feedback about your genetic information. However, the overall findings of the study will be
shared through usual medical publications and lectures.

Any individual information will remain confidential and will not be released to anyone else, for example
your employer or your insurance company. No material that could personally identify you will be used in
any reports on this study.

**WILL MY HEALTH RECORDS BE ACCESSED?**

With your consent, information may also be obtained from your hospital medical records. As this is a long-
term study the information you provide will become more valuable over time. We request your permission
to obtain information about future hospital admissions and cause of death from the administrative records
of Ministry of Health should either occur.

**WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?**

The information from this study will be used to help improve the quality of the care provided to people with
heart problems, and may help to find new treatments for your children and grandchildren’s generation.
We hope to show that treatment can be improved by understanding peoples’ genetic and environmental
factors and how they cause heart disease.

There is no risk in being part of the study. Taking the blood sample may cause minor discomfort and
occasional bruising.

**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 the study
coordinator ………….. or the Principal Investigator Associate Professor Malcolm Legget on 09-9236713

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@hdc.org.nz

For Māori Health Support or to discuss any concerns or issues regarding this study, please contact:

Auckland Hospital: If you require Māori cultural support 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

Christchurch Hospital: Kathy Simmons
Ngā Ratonga Hauora Māori
Phone 03 364 0640 Extension: 86160 Fax: 364 6018

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

- **Phone:** 0800 4 ETHICS
- **Email:** hdecs@moh.govt.nz