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| hw_logo_b&w_new**Participant Information Sheet** |  |
| Study title: | IMPACT |
| Locality:  | Waikato Hospital | Ethics committee ref: | **13/CEN/209** |
| Lead investigator:  | Dr Gerry Devlin | Contact phone number: | 07 839 8899 or 07 839 7136 |

You are invited to take part in a study which will compare 2 anti-clotting medications after Coronary Artery Bypass Graft (CABG) surgery. 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 pull out of 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. One of the study doctors 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.

WHY HAVE I BEEN INVITED TO TAKE PART IN THIS STUDY?

You are eligible for the study because you have been admitted to hospital with either angina or a heart attack and have been referred for Coronary Artery Bypass Graft (CABG) surgery.

You may not take part in this study if you have had previous bypass surgery or if you are taking medications to prevent blood clots such as Warfarin. You may also not take part if you have active problems with bleeding or a stomach ulcer.

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?

The purpose of this study is to find out which of 2 anti-clotting medications will be better at preventing blocking up of the vein grafts following CABG surgery. Both these medication are approved in New Zealand and other parts of the world. The 2 medications are Clopidogrel and Ticagrelor.

It is already common practice to give one of the 2 medications being studied. Clopidogrel has been used for several years and Ticagrelor is a newer medication. There is some evidence that Ticagrelor is superior, but the evidence needs to be strengthened by more studies for us to be certain which is the best medication to use.

If you agree to take part in this study, you would be randomly allocated (like tossing of a coin) to receive either Clopidogrel or Ticagrelor for 12 months.

This study is “Investigator initiated” as opposed to initiated by a pharmaceutical company.

Dr Gerry Devlin, Cardiologist at Waikato Hospital, is the Principal Investigator of the Study. He can be contacted through the Waikato Hospital switchboard, ph 839 8899.

The study has ethical approval from the Central Health and Disability Ethics Committee in New Zealand.

What will my participation in the study involve?

If you take part in the study you will receive (by random assignment) either Clopidogrel 1 tablet daily or Ticagrelor 1 tablet twice a day for 12 months.

Clopidogrel or Ticagrelor will be obtained with a prescription from the hospital doctor at your local pharmacy. After 3 months your own doctor will prescribe this medication for you for the remainder of the 12 months.

You will also be asked to take enteric coated Aspirin 100 mg 1 tablet daily for the duration of the study and indefinitely as this has been proven to be of long term benefit in reducing blocked arteries and vein grafts.

Study participation is for 12 months. A study coordinator will phone you at 3, 6 and 9 months following surgery to check that you are still taking the study tablets as these are very important to help prevent blood clots and resulting blocking up of the new vein grafts.

At 12 months after your surgery you will be asked to have a CT coronary angiogram (CCTA) to check the patency (lack of blocking or narrowing) of your new vein grafts.

**Heart Scan – CCTA**

After 12 months the study requires you to have a special type of X-ray of your heart called a coronary computed tomography angiogram [CCTA]. It involves an x-ray machine that uses a computer to make pictures of your heart and its arteries. The CCTA is only done for the study research purposes. It will show us whether the surgical vein grafts are clear of any blockages.

For the CCTA you will:

1. Have a small plastic tube inserted into a vein (IV) so that dye can be injected. The dye will help show the arteries in your heart.
2. Your pulse and blood pressure will be monitored during the CCTA.
3. You may be given medicine to slow your heart down to get better pictures.
4. You may be given medicine (GTN spray) to help dilate your arteries.
5. You will be asked to hold your breath while the machine takes the pictures, which only takes a few seconds.

CONFIDENTIALITY

As part of the study, health information about you will be entered in the study records. This will be taken from your medical record. We will also ask at each clinic visit and phone contact how you have been and this will be recorded in the study information during the study. None of this information or the presentation of the study results will in any way identify you. All study files are kept in a locked and secure location. AstraZeneca, LP, the manufacturer of the study drug, Ticagrelor will also have access to your health information.

What are the possible benefits and risks of this study?

Both Clopidogrel and Ticagrelor increase the risk of bleeding this can potentially happen in the eye, coughing blood, nose or gum bleeds, blood in urine, bloody/ black bowel motions, or increased bleeding from injury and bruising. The risk of a serious or dangerous bleed occurring in the brain is 0.4%.

Any sign of even mild bleeding should be reported to the study doctor Dr Gerry Devlin ph 839 8899, the study clinic on 839 7136, your own doctor or the hospital emergency department.

Ticagrelor may cause a sensation of shortness of breath.

Clopidogrel may cause a rash, itching, and diarrhoea.

Most people using these medications do not have any side effects.

You may not receive any direct personal benefit from taking part in this study. The study aims to find out which is the best treatment. This will be of benefit to future patients.

**CCTA Risks**

The main risk of the CCTA is exposure to radiation. Radiation is measured in mSv (millisievert) units. In this study, the estimated total radiation dose you will receive from one CCTA scan is on average 4-6 mSv. A person living at sea level for 1 year is exposed to about 3 mSv of natural radiation, so the expected radiation dose from one CCTA is around 1-3 times that amount. In comparison, the estimated radiation for other tests is:

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| Test | Radiation Dose |
| chest X-ray | 0.05 mSv |
| cardiac catheterization | 5-7 mSv |
| PCI | 10-16 mSv |
| nuclear stress test | 12-30 mSv |

There may be side effects from medications that may be used during the CCTA. You will be monitored throughout the procedure for these side effects and treated, if necessary.

Beta blockers (slow the heart) may cause a very slow heart rate or low blood pressure.

Nitroglycerin can lower blood pressure and may cause headache.

Other known risks of CCTA include allergic reactions to the x-ray dye. If you have a history of allergy to X-ray dye, please tell the study staff. To reduce the risk of a severe allergic reaction you may be given special medication for 24 hours before the test.

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| Rare Serious Allergic Reactions1 in 2500 to 1 in 1000 chance or less (.04% to .1%) | Less Common Allergic Reactions2 in 100 to 10 in 100 chance or less (2% to 10%) |
| * Difficulty breathing
* Swelling in the throat
* Low blood pressure
* Heart stoppage (cardiac arrest)
 | * Itching/hives
* Nausea/vomiting
* Mild warmth feeling

If you have a mild allergic reaction it will be treated with a common allergy medicine |

A rare risk of CCTA is kidney damage from the x-ray dye.

If the CCTA shows a problem other than narrowed heart arteries (such as a lung problem), your study doctor will be informed and will contact your regular doctor about the problem. Your doctor may ask you to have other tests to learn about and/or treat that problem.

With your permission, we will inform your GP of your participation in the study.

Who pays for the study?

You will not incur any costs by taking part in this study.

There will be no payment for taking part. Petrol vouchers can be provided to you to cover your travel costs for the 12 month visit.

What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. 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.

What are my rights?

Participation in this study is voluntary. You are free to decline to participate, or to withdraw from the research at any time, without experiencing any disadvantage.

As a study participant you have the right to access information about you that has been collected as part of the study

You will be told of any new information about adverse or beneficial effects related to the study medications that becomes available during the study that may have an impact on your willingness to continue in the study

What happens after the study?

The information collected during the study will be stored for 15 years in a secure facility.

The study findings can be communicated to you on completion of the study. This may take a few months after the last study participant has completed the study.

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:

Dr Gerry Devlin, Clinical Unit Leader Cardiology ,Cardiac and Thoracovascular Surgery Interventional Cardiologist Waikato Hospital.

Phone: 839 8899.

Email: Gerard.Devlin@waikatodhb.health.nz

Or the Study Coordinator team at Cardiology Clinical Trials Unit.

Phone: 839 7136

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 Maori health support please contact :

Manager, Te Puna Oranga, Waikato Hospital

 Telephone number: 07 839 8899

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

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| hw_logo_b&w_new**Consent Form** | *hw_logo_b&w_new* |

**If you need an INTERPRETER, please tell us.**

**Please tick to indicate you consent to the following**

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| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  | Yes 🞏 | No 🞏 |
| I have been given sufficient time to consider whether or not to participate in this study. | Yes 🞏 | No 🞏 |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 | No 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes 🞏 | No 🞏 |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting and processing my information, including information about my health. | Yes 🞏 | No 🞏 |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. | Yes 🞏 | No 🞏 |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. | Yes 🞏 | No 🞏 |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | Yes 🞏 | No 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 | No 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 | No 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

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| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: |
| Signature: | Date: |