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INFORMATION AND CONSENT FORM

Research Protocol Title: Ticagrelor compared to clopidogrel in acute coronary syndromes - the TC4 comparative effectiveness study

Protocol Number: 2019-4530

Funded: the Canadian Institute of Health Research

Principal Investigator: Dr. James Brophy
MUHC Division of Cardiology

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INTRODUCTION

We are inviting you to take part in this research study because you were admittedto the McGill University Health Centre for an acute heart problem and are being treated with Aspirin along with a second blood thinning drug,either clopidogrel (Plavix) or ticagrelor (Brilinta).

However, before you accept to take part in this study and sign this information and consent form, please take the time to read, understand and carefully examine the following information. You may also want to discuss this study with your family doctor, a family member or a close friend.

We invite you to speak to the researcher responsible for this study ("the researcher") or to other members of the research team and ask them any questions you may have about this study. Please also ask a member of the research team about any parts of this consent form you do not understand.

BACKGROUND

Many heart problems result from narrowed arteries of the heart.This narrowing leads to an increased chance of a blood clot that completely or nearly completely blocks all blood flow to a part of the heart muscle. Aspirin is a blood thinner that can help preventprevent blood clot formation and reduce heart attacks. The beneficial effect of Aspirincan also beimproved with the addition of a second blood thinner. Many studies have shown that the combination of Aspirin and clopidogrel (Plavix) is effective. A recent study compared the new combination of Aspirin and ticagrelor (Brilinta) to the standard therapy of Aspirin and clopidogrel (Plavix) and found the new combination to be more effective. However, very few of the patients in this study were from North America. For these North American individuals there was no clear advantage observed between the two drug combinations. The Food and Drug Administration in the USA approved the new drug, ticagrelor (Brilinta), but recommended that more research was necessary in North American patients to clarify the situation.

At the MUHC, all patients receive two blood thinners following a heart attack. Usually,MUHC doctors prescribe the Aspirin and clopidogrel (Plavix) combination but certain doctors prefer the newer combination of Aspirin and ticagrelor (Brilinta). In other hospitals, the newer drug combination is being prescribed more often. However, it must be repeated that there is no convincing evidence that one drug combination is better or safer than the other.

PURPOSE OF THE RESEARCH STUDY

The goal of this study is to try and answer the question of which blood thinning drug combination is better following a heart attack, Aspirin and clopidogrel (Plavix) or Aspirin and ticagrelor (Brilinta)?

DESCRIPTION OF THE RESEARCH PROCEDURES

This research study will take place here at the McGill University Health Centre (MUHC).There are no extra doctor visits related to this research project.

1. Overview of study participation

The following procedures will be performed as part of the study:

Study medication:

Given the uncertainty about the risks and benefits of the blood thinning drugs clopidogrel (Plavix) and ticagrelor (Brilinta), our Division of Cardiology has decided to give the different drug combinations according to specific 2-month time frames. All patients requiring two blood thinners, also known as DAPT (dual anti-platelet therapy) will randomly receive one of the two possible drug combinations. This will occur whether you participate in this research study or not.

To repeat the two drug combinations are: Aspirin and clopidogrel (Plavix) or Aspirin and ticagrelor (Brilinta)depending on when you are admitted to hospital.A member of the study team

will tell you which medications you have been given.Participation in this study will not otherwise alter your medical care and will not require any extra hospital visits.

Access to medical records:
By participating in the study, you agree that we may access your electronic medico-administrative health records (medical charts) starting from now and continuing for a maximum of 5 years to obtain among other things information about doctor visits, hospitalizations, diagnoses and medications. These electronic medical health records will be obtained from your hospital records, and from the Ministry of health and social services (MSSS), the Régie de l'Assurance maladie du Québec (RAMQ), the Institute de la statistique du Québec (ISQ) and from your "Dossier de santé Québec".

Blood test (optional):
If you agree,there will be an extra blood test performed with your regular blood tests which will be stored in the MUHC TC4 Biobank. The sample may be used in the future to investigate new genetic or non-genetic cardiac tests. You may participate in the research project without agreeing to the blood test. If you do agree to the blood test, you will be asked to sign a separate consent form.

Risks

As these are established treatments there is minimal risk to your participation. Your participation in this project will not influence decisions made by your doctors for your care. All medical decisions will, as usual, be made strictly in your best interests.

A possible risk associated with this study is a breach of confidentiality or use of your personal information by a third party. To limit this risk, we will take the steps to protect your confidentiality described in the Confidentiality section, below

Benefits

Your participation will not bring you any advantages. However, your participation may help future patients by generating knowledge as to which drug combination is superior.

Alternatives to study participation

Even if you choose not to participate in the study, be assured that you will still receive one of the 2 drug combinations as an essential part of your treatment. You do not have to participate in this study to receive care or treatment.

VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW

Your participation in this study is voluntary. Therefore, you may refuse to participate. You may also withdraw from the *ongoing* project at any time, without giving any reason, by informing a member of the study team. Your decision not to participate in the study, or to withdraw from it,

will have no impact on the quality of care and services to which you are otherwise entitled. You will be informed in a timely manner if any information becomes available that may impact your willingness to continue participating in this study.

The researcher or the Research Ethics Board may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

If you withdraw or are withdrawn from the study, you may also request that the data already collected about you be removed from the study. If you request that your data be removed and the information already collected about you can be identified as yours it will be destroyed. If the data has been anonymized or was always anonymous (i.e. does not contain any information that can be used to identify you), the data will continue to be used in the analysis of the study.

Confidentiality

During your participation in this study, the researcher and his/her team will collect and record information about you. They will only collect information necessary for the study.

The following information may be collected: information from your medical chart, including your identity, concerning your past and present state of health, your lifestyle, as well as the results of the tests, exams, and procedures that you will undergo during this research project. Your research file could also contain other information, such as your name, sex, date of birth and ethnic origin.

All the information collected during the research project will remain confidential to the extent provided by law. You will only be identified by a code number. The key to the code linking your name to your study participant number will be kept by the researcher.

The study data will be stored for up to 25 years, as requested by scientific funding agencies, by the researcher responsible for the study.

For auditing purposes, the research study files which could include documents that may identify you may be examined by a person mandated by the study sponsor, the institution, or the Research Ethics Board. All these individuals and organizations adhere to policies on confidentiality.

Compensation

You will not receive financial compensation for participating in this research study

SHOULD YOU SUFFER ANY HARM

Should you suffer harm of any kind following any procedure related to the research study, you

will receive the appropriate care and services required by your state of health.

By agreeing to participate in this research project, you are not waiving any of your legal rights nor discharging the researcher, the sponsor or the institution, of their civil and professional responsibilities.

CONTACT INFORMATION

If you have questions or if you have a problem you think may be related to your participation in this research study, or if you would like to withdraw, you may communicate with the researcher or with someone on the research team at the following number:

Study Co-ordinator:
Nina Mamishi–514-843-1502

Principal Investigator:
Dr. James Brophy – 514-934-1934 ext. 36771

For any question concerning your rights as a research participant taking part in this study, or if you have comments, or wish to file a complaint, you may communicate with:

The Patient Ombudsman of the McGill University Health Centreat the following phone number:

Lynne Casgrain – 514-934-1934 ext. 48306.

OVERVIEW OF ETHICAL ASPECTS OF THE RESEARCH

The McGill University Health Centre Research Ethics Board reviewed this research and is responsible for monitoring the study.

CONSENT FORM: Accessing Medical Records

Research Study Title: **Ticagrelor compared to clopidogrel in acute coronary syndromes - the TC4 comparative effectiveness study**

SIGNATURES

Signature of the participant

I have reviewed the information and consent form. Both the research study and the information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above.

1) I authorize the study team to have access to my electronic medical records (hospital, MSSS, RAMQ, ISQ and "Dossier de santé Québec") for up to 5 years.

   Yes ☐ No ☐

2) I authorize a member of the research study to contact me in the future to ask if I am interested in participating in other research.

   Yes ☐ No ☐ If yes, please provide contact information: _____

Name of participant Signature Date

Signature of the person obtaining consent

I have explained the research study and the terms of this information and consent form to the research participant, and I answered all his/her questions.

Name of the person obtaining consent Signature Date