Informed Consent From - New Antiplatelet Medicine

You are having signs and symptoms that suggest a blocked heart artery. Your may need to have a procedure to open up one or more blood vessels using a stent. Sometimes blood clots can form inside stents and block blood flow. Plavix (Clopidogrel) is currently the standard drug used to prevent these blood clots. You are being asked to be a part of a study testing a new medicine to prevent clots in stents.

Your doctor thinks you are an appropriate candidate for this study, but you do not have to be in it. **It is your choice. Either way you will be treated with the highest quality care**. This form tells you about the study. Please ask questions about anything that is not clear.

What is the study about?

There is an investigational drug, called Antiplatelet, which is being tested in hospitals worldwide to see how well it prevents the formation of blood clots in stents. Antiplatelet is a lot like Plavix but is given as an IV medicine. This study is designed to compare the safety and effectiveness of using Antiplatelet at the time a patient receives a stent with using Plavix at the time of the stent.

How is this different from what is done normally

Normally, when people have a procedure to open up a blocked heart artery they are given the first dose of Plavix right after getting the stent, while they are still in the procedure room. The dose (number of pills) of Plavix is determined by the doctor. For this study, some patients will get Plavix pills and an IV placebo (salt water) solution right after the stent. The other patients will get IV Antiplatelet and placebo pills right after the stent. The placebo IV solution and pills help to make sure that doctors and patients don't know who gets which medicine. After that first dose of medicine, all patients will be treated with Plavix only.

How is it decided which group you will be in?

A computer will randomly assign you to be in one treatment group or the other. *You will have an equal (50/50) chance of being assigned to either group.*

What will be required of you?

Your participation in the study will last approximately 5 weeks. You will receive 2 follow up calls during that period to check on your recovery.

What are the possible benefits of being in the study?

The main goal of this study is to understand if Antiplatelet is a safe and effective treatment. Being in this study may not benefit you directly. It is possible that those receiving the study drug in addition to Plavix will experience further reduction in the chance of blood clots normally associated with procedures of this type. It is our hope that in the future other patients may benefit from the information learned through this study.

What are the possible risks of being in the study?

There are bleeding risks associated with both drugs. The risks of Plavix are not any different whether you are in the study or not. Additional risks associated with Antiplatelet include, stomach discomfort, back pain, chest pain and shortness of breath. A complete list of risks can be found in the accompanying study information sheet.

What is the alternative to being in the study?

The alternative to being in the study is to be treated with Plavix.

What happens if you are harmed by being in the study?

If you are harmed as a result of being in this study, the study sponsor will pay for costs associated with that injury. Additional information can be found in the study information sheet.

Will insurance cover treatment in the study?

Any medical services you need as a result of participating in the study will be covered by the study. There will be no extra charges to you or your insurance for being in this study. Payment for treatment of your heart attack will be handled just as it would be if you were not in the study, according to the terms of your health insurance policy.

Will you be paid for being in the study?

You will not be offered payment for being in this study.

Will your information be kept private?

Yes. Your information private in accordance with research regulations. We will use a code rather than your name to label your information, and we will not identify you in research reports. However, your records may be reviewed by study sponsors or the federal Food and Drug Administration, as required by research regulations. See the study information sheet for details on privacy rules and procedures if you have questions.

What can you expect from the researchers?

If researchers find out about unexpected risks or dangers of the study, they will inform you and may remove you from the study if needed. They will honor any decision you make to withdraw from the study at any time. Your medical care will not be compromised in any way.

We want to answer questions you may have about the study now or at any time. If you decide to participate, your doctor or someone from the study team will talk with you again after your procedure and answer any questions you may have about the study.

Whom can you contact if you have questions or concerns?

The doctor, nurse, study team etc. XXXX

A description of this study is available on http://www.ClinicalTrials.gov. This website does not identify patients. At most, it will include a summary of the results. You can search this website at any time.

Consent

Please **print** your name, **sign**, and **date** below if you agree to be in the study. By signing this consent and authorization form, you will not give up any of your legal rights.

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Name of Participant

_____ _____ _____

Signature of Participant (18 or older and able to consent) **Date** **Time**

_____ _____ _____

Signature of Legally Authorized Representative with authority for research decisions **Date** **Time**

_____

Relationship to Participant or Authority of Legally Authorized Representative

_____

Phone number for Legally Authorized Representative

_____

Name of Person Conducting Informed Consent Discussion

_____ _____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**