Informed Consent Form – Crushed versus Whole Pill

You are having a heart attack. You are being asked to be a part of a study about an approved medicine that is used to treat heart attacks. The first dose of the medicine will be given at the end of the catheterization procedure you are about to have. This study is testing whether the first dose of the medicine is more effective taken as a whole tablet or crushed up.

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 receive 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?

Effient keeps clots from forming inside of stents used to treat heart attack. This study is testing whether crushing up the first tablet helps the medicine work faster. Patients in this study will be assigned to one of two groups. One group will take the tablet crushed up. The other group will take the tablet whole. Both groups will be treated the same in all other ways.

How is this different from what would be done normally?

Normally, patients take the first dose of Effient as a whole tablet. Taking it crushed up is investigational. Being in this study only affects how you take the first dose of the medicine.

How is it decided which group you will be in?

If your doctor decides to treat you with Effient after your catheterization and you have agreed to be in this study, a computer will randomly assign you either to take the first tablet crushed up or to take the first tablet whole. *You have an equal (50/50) chance of being in either group***.**

What will be required of you?

Your participation will last about 24 hours. After taking the first tablet crushed or whole, you will have blood work done to test blood clotting and drug levels. You will have blood drawn 6 times over 24 hours.

What are the possible benefits of being in the study?

The main goal of this study is to improve care for patients with heart attacks. Being in this study may not benefit you directly. It is possible that the medicine may work faster when taken crushed rather than whole, but doctors do not know which way is better.

What are the possible risks of being in the study?

The most significant risk associated with Effient is bleeding. This risk is not expected to be influenced by whether you take the first dose crushed or whole. For more information on risks, please see the accompanying study information sheet.

What is the alternative to being in the study?

The alternative is simply to take the Effient tablet whole, according to standard hospital practice.

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. For additional information, please see 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 receive payment for being a part of this study.

Will your information be kept private?

Yes. Your information will be kept 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**