Informed Consent Form - Balloon Pump for Heart Attack

You are about to have a procedure to open up a blockage in your heart artery that is causing a heart attack. You are also being asked to be a part of a study about heart attack treatment. The study is testing whether using a tool called a balloon pump can reduce heart damage.

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?

The study is testing whether a balloon pump helps patients with heart attacks like yours. A balloon pump is a long balloon inserted through the groin into the body's major artery (the aorta). It can help the heart beat better and improve blood flow to the heart. Balloon pumps are not new. They have been used for years to treat patients whose hearts do not pump well.

How is this different from what would be done normally?

This study is testing whether putting in a balloon pump *before* using a catheter to open up the blocked heart artery (a procedure called "angioplasty and stenting") makes the heart have less damage and improves heart function. In order to learn whether balloon pumps help patients with heart attacks like yours, some patients will have a balloon pump put in and others will not.

Has this balloon pump been used before?

Yes. Balloon pumps are not new. They have been used for many years to treat patients whose hearts do not pump well. Using a balloon pump *before opening the artery* to reduce heart damage is considered investigational.

How is it decided which group you will be in?

A computer will randomly assign you to be in one treatment group. *You have an equal (50/50) chance of being in either group.* One group will have a balloon pump before the artery is opened up. The other group will have the standard procedure to open the artery but not be treated with a balloon pump.

If you are assigned to be treated with a balloon pump…

The balloon pump will be inserted through a blood vessel in your groin while you are in the catheterization room. After the balloon pump is in place, your doctor will use another catheter (in your other groin or your arm) to open the blocked heart artery.

After your procedure, the balloon pump will stay in for 12 to 24 hours. It will then be removed. While the balloon pump is in your body, you will need to lie on your back. *If at any time your doctor thinks that the balloon pump is not appropriate for you, it will be removed.*

If you are NOT assigned to be treated with a balloon pump…

A balloon pump will not be used. Your doctor will perform the standard procedure and insert a catheter through your groin or arm and open up the blocked heart artery. *If your doctor decides later that you need a balloon pump because your heart is not pumping well, your doctor may decide to use a balloon pump*.

What will be required of you?

You will have an MRI test 3 to 5 days after your procedure. The MRI takes a picture of your heart. The MRI will tell how well the heart is functioning and what amount of heart damage has occurred from the heart attack. The scan can take up to an hour. If you know that you would not be able to do this MRI test, you should not participate in this study.

You will receive a telephone call in 1 month and in 6 months to see how you are doing.

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. If the balloon pump helps to reduce heart damage and improve heart function, it is possible that your heart attack may be more effectively treated.

What are the possible risks of being in the study?

The risks of standard treatment for heart attack will be present whether you decide to be in this study or not. The risks from being in this study are related to having a balloon pump and the MRI.

Risks from the balloon pump:

- Damage to the artery where the balloon pump is placed

- Bleeding or bruising in the groin
- Infection
- Low blood counts
- Rare risks: stroke, death

Risks from the MRI:

- Injury if you have metal in your body (we will ask you again before the MRI)
- Injury if your kidney function is reduced (we will check kidney function before the MRI)

A complete list of risks is included in the accompanying study information sheet.

What is the alternative to being in the study?

If you choose not to be in the study, you will receive the highest quality care to open up your blocked artery and treat your heart attack. A balloon pump would be used if you develop very low blood pressure or poor heart function. *Your care will not be compromised by not being in the study. You can stop participating in the study at any time*.

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

You will receive all necessary immediate care from this medical center. If it is determined that you have been harmed by being in this study, the medical equipment company sponsoring this study will pay for the costs for treatment not otherwise paid for by insurance. For more information about this please see the study information sheet.

Will insurance cover treatment in 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 will be kept private in accordance with research regulations. We will use a special code to identify your information. We will not identify you in any reports. However, your records may be reviewed by study sponsors or FDA, as required by federal and state 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. However, you do need to decide whether to be in the study before you have the catheterization procedure. If you decide to participate, your doctor or someone from the study team will also 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.

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 Consent Discussion **Date** **Time**