CONSENT
FOR THE OCCLUDED ARTERY TRIAL (OAT)
(For patients who have not had angiography yet)

Overview

Doctors at _____ hospital are inviting you to join the occluded artery research study because you had a heart attack within the past 28 days. Heart attacks are caused by a blockage in vessels (arteries) that bring blood to the heart. Your doctors have not yet checked if the artery of your heart attack is still blocked but the doctors believe it might be. They will take pictures of your heart to confirm the blockage. These pictures may be performed by your doctor as part of routine care or will be performed as part of this research study if you agree to participate. If the artery causing the heart attack is totally blocked, you will be eligible to participate in this study. If the artery is already open, you can not join this study and further care will depend on your doctor's advice.

Doctors have used heart balloons and stents (as described below) to treat blocked arteries in cases where severe angina (chest pain) is present. However it is not known whether it is beneficial for your condition. This study is designed to find out whether opening blocked arteries is beneficial for patients like you. Doctors are working on this study in about 320 hospitals. The study will involve 3,200 patients. You may join the study if you agree with the research rules that apply to patients in this study. Taking part in this study is your choice. You may refuse to join or leave the study at any time without affecting your health care.

Purpose

This is a study of what to do about a heart artery that stays blocked in the days after a heart attack. Risks for patients who had heart attacks include repeat heart attack; swollen legs, loss of energy or shortness of breath due to weak heart muscles; feeling dizzy or out of sorts due to changes from a normal heart beat pattern; and death. This study is designed to find out the value of opening blood flow in the blocked artery with a small balloon inserted through the vessel in your upper thigh or arm, as described below. All patients in the study will get usual standard care that may include electrocardiograms, oxygen, drugs to stop the blood from clotting, and other heart drugs. If you join this study, you will be assigned by chance --- like tossing a coin --- to one of two groups. One group will have the artery opened. This group will also get the usual health care. The other group will get usual health care only. Usual health care for your condition includes a number of heart drugs but does not include opening blood flow with a balloon or device and stent. The usual health care in this study is the current standard of care.

Procedures

Study doctors will take a blood sample (about one tablespoon) for a pregnancy test on any woman who could be pregnant. Pregnant women should avoid taking x-ray pictures like those for this study. Pregnant women may not join this study. For research purposes, approximately a teaspoon of blood will be drawn up to 4 times to check for heart muscle damage.

You will have x-ray pictures of your heart's arteries if your doctor asks you to have them as part of your own medical care or as part of this research study. If the heart attack artery is open on x-ray pictures, you will not be part of this study. If the heart attack artery is totally blocked, you may join the study.

Doctors put a dye into the heart through a long plastic tube to take x-ray pictures of the heart. Study doctors can reach the artery in your heart by placing the tube in an artery in your upper thigh or arm. If you join the study and are in the group of patients who get blocked arteries opened right away, your doctors will open the artery.

The opening procedure (angioplasty) is done with a long plastic tube placed in the artery in the upper thigh or arm and advanced to the blocked artery. This tube has a balloon or cutting device at its end. Doctors use x-ray pictures taken with a dye to put the end of the tube in the

blocked artery. The doctors will fill a balloon at the end of the tube with harmless liquid to push open the block or use the cutting device to remove the block. Blood flows through the artery after the block is gone. The tube used to open the artery is taken out. A second tube is put in its place to implant a stent.

A stent is a small metal wire mesh. A stent is about the size of a spring in a ballpoint pen. The stent moves into the newly opened artery over a balloon at the end of the second tube. When the stent is at the point where the old block was, the doctors fill the balloon with harmless liquid to push open the stent and fix it in place in the artery. After the stent is in place, the doctors empty the liquid through the tube and remove the balloon. They leave the stent in the artery to hold it open.

Risks

The risks of the x-ray pictures of your heart's arteries and the procedures to open and hold open blocked arteries in this study include stroke, heart attack and urgent coronary artery bypass graft surgery. The combined risks for the occurrence of any of these three complications is less than 3 in 100. The risk of procedural death is estimated to be between 1 in 100 and 1 in 1,000. In addition, angioplasty may rarely cause a leak of blood around the heart. In this study, the risk of any bad effect from the increase in the amount of x-rays used to take pictures of the heart over and above the x-rays for usual health care is very small (less than 1 in 10,000). Other risks include irregular heart beats (less than 2%), high or low blood pressure (less than 2%), allergic reaction to the x-ray dye or medication (less than 2%), kidney failure (less than 1%) and infection (less than 2%). Less serious complications including bleeding (which may include need for transfusion), bruising and lump formation (hematoma or false aneurysm) at the puncture site in the upper thigh or arm may require ultrasound and/or minor surgery (less than 2%).

Several medications which thin the blood will be used during and following the angioplasty procedure as part of standard care. These may include heparin, aspirin, ticlopidine, clopidogrel, and glycoprotein IIb/IIIa inhibitors. In a small number of patients, the artery will re-block during or soon after opening. This sudden closure may lead to a heart attack, the urgent need for repeat opening, emergency surgery, or death. As blood clots can cause sudden closure, these blood thinning medicines described above, will be used to lower the chance of blood clotting. These medicines are part of standard treatment to open a blocked heart artery. A stent may move from the site it is placed to a site further down the blood vessel.

An open artery may re-block slowly at a later time. The usual time for a re-block is three to six months after opening. Slow re-block may lead to chest pain (angina), a need for another balloon angioplasty procedure, or other signs of heart disease.

You may experience discomfort when needles are inserted into veins of your arms to obtain blood samples. You may experience a slight bruise, discoloration, or swelling at the site of the needle stick.

Follow-Up

The staff of _____ hospital and/or representatives of the OAT Economics and Quality of Life (EQOL) Coordinating Center at Duke University may contact your doctor(s) and hospital(s) to obtain copies of your medical records, tests and bills for up to 5 years (the length of the study). When you are enrolled in the study, they will ask you questions about your health and how you are feeling. After enrollment, they will contact you by telephone every four months for up to 5 years (the length of the study) to see how you are doing and to help provide information about your treatment. The calls will take about 15-30 minutes. You may refuse to answer any question. Instead of being contacted by telephone, you may choose to visit the study office. You may be visited by a study coordinator or investigator during your hospital stay(s) or be contacted by mail.

You may be asked questions about your health and how you are feeling by representatives of the OAT EQOL Coordinating Center to ensure standardization of interviews

across study participants. Portions of this interview may be audiotaped by your hospital staff. No identifying information will be included on the tape. The tape will be sent to the OAT EQOL Coordinating Center at Duke University for analysis and will be destroyed at the end of the study.

Benefits

With these procedures some patients may have better heart function, better overall health, and, perhaps, longer lives if opening the blocked artery is helpful. The results of this study may be useful to heart attack patients in the future.

Other Choices

As an alternative to participating in this study, you can plan your own treatment with your doctor without limitation of choices. This treatment could include drugs to stop blood from clotting, other heart drugs, procedures to open blocked heart arteries and coronary artery bypass surgery.

Cost and Payment

You will not be paid for your part in this study. The same charges will apply for the days of your hospital stay whether or not you join the study. The hospital will charge as usual for any treatments you have, such as treatments to open blocked arteries and drugs. In the event injury occurs to you from the research project, treatment will be available, if appropriate, at _____ hospital. However, there are no special arrangements for compensation or payment for treatment solely because of your part in this research study.

Privacy

Your data in this study will remain private. When the results of this study are made public, the doctors will not use your name or let anyone know about you personally. The leading study doctors, study staff, and the hospital's patient's rights board may review your files. Government agencies (federal, state and local) may inspect any medical/research records on legal demand but all efforts to maintain your confidentiality will be made.

Rights

You may refuse to take part in or may leave this study at any time without affecting your present or future care at this hospital. Dr. _____ explained this study to you. You have had time to ask questions and discuss any concerns you may have about the study. If you have any further questions, you may call Dr. _____ at _____ (tel. #). You know that you may withdraw from this study at any time without affecting your health care. Part of the Patient Representative's job is to ensure that doctors and other staff honor patient rights in research projects here. You may call the Patient Representative to talk about any questions you may have about your rights or if you do not like some part of the study. The Patient Representative_____telephone number is _____.

Consent

You are signing below because you agree to join this study. You may keep a copy of this consent form.

_____ _____

Patient Signature Date

_____ _____

Investigator Date

_____ _____

Witness Date