

TITLE: The MASS COMM TRIAL-- A Randomized Trial to Compare Percutaneous Coronary Intervention Between Massachusetts Hospitals With Cardiac Surgery-On-Site and Community Hospitals Without Cardiac Surgery-On-Site

SPONSOR: Massachusetts Community Hospitals with oversight from Massachusetts Department of Public Health

You are asked to join this research study. Your participation is voluntary. Before deciding if you want to join in this research study, it is important that you read and understand the following explanation of the proposed procedures. This consent form describes the purpose, procedures, benefits, risks, discomforts and safety measures of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to what the results of the study will be.

It is important that you give complete and accurate information about your medical health to the study staff. If the study staff is not aware of all of your medical health conditions, it is possible that your health could be accidentally harmed by joining this study.

INTRODUCTION

You are asked to join this research study because you have been diagnosed with a condition called myocardial ischemia. This condition means that you have a blockage in your heart vessel that limits the amount of blood flow to your heart muscle, because the blockage narrows your heart artery. When blood flow is limited, less oxygen gets to your heart muscle and you may be at increased risk for a heart attack. To treat this blockage, you will have a procedure known as a cardiac catheterization, a procedure that uses a hollow plastic tube (catheter) placed into your leg vessel (femoral artery) and passed up and into your heart. Through this catheter tube other devices known as small balloons and stents (a hollow metal tube) will be used to open the blockage in your heart. This medical procedure is also known as percutaneous coronary intervention (PCI). You will receive a separate consent form that will explain this procedure and its risks and benefits.

BACKGROUND

Cardiac catheterization is performed in different medical settings according to recommendations made by professional medical societies like the American Heart Association (AHA), American College of Cardiology (ACC) and Society for Cardiovascular Angiography and Interventions (SCAI) and is monitored by the Massachusetts Department of Public Health (MA-DPH) in this state. Based upon these current recommendations, PCI at hospitals with no cardiac surgery on their site (non-SOS) is limited to only emergency treatment for heart attacks. There are risks to performing PCI for both emergency heart attacks and non-emergency (elective) heart problems. These risks can be low, but if emergency complications happen in hospitals with no surgery on site (non-SOS) it is possible that the inability to perform emergency cardiac surgery to correct the complication may put the patient at additional risk or cause them to have much worse outcomes. This additional risk has been an important reason in the past for limiting PCI to only emergency procedures at hospitals with no cardiac surgery on site (non-SOS).

Recent advances in the technique and devices for PCI have helped to reduce the need for emergency cardiac surgery, which happens in approximately 1 in 1,000 procedures. This low complication rate combined with the option to transport a patient via ambulance from the non-SOS hospital to a hospital that offers cardiac surgery on-site (SOS), has led doctors from both non-SOS and SOS hospitals and the MA-DPH to study if both emergency and non-emergency PCI procedures can be performed at non-SOS hospitals.

PURPOSE

This study is being done to learn if there is a difference in the short-term (30 days) and long-term (12 months) outcomes of patients who have treatment with percutaneous cardiac intervention (PCI) between SOS hospitals versus non-SOS hospitals. The study will compare the rate of complications (death, heart attack, bleeding, stroke, or repeat attempts to open the narrowing by another PCI or bypass cardiac surgery) during the 12 months following the procedure.

The goal will be to show that elective PCI performed with no cardiac surgery on site (non-SOS) has the similar (non-inferior) complication rates at 1 and 12 months following the procedure, as does elective PCI performed at hospitals that have on site cardiac surgery (SOS hospitals). Approximately 6000 patients will be studied: 4800 patients will be enrolled from the non-SOS sites and 1200 patients will be enrolled from the SOS hospital sites.

STUDY DESCRIPTION

You will be one of about 4,800 patients that will participate at one of 7 non-SOS hospitals in Massachusetts that have been allowed for this study to perform elective PCI without cardiac surgery on site. About 75% of these subjects (3,600 patients) will undergo PCI at the non-SOS hospital, while 25% of these subjects (1,200 patients) will be transferred to one of 7 participating hospitals with cardiac surgery on-site (SOS) to have their PCI. The chance of being assigned to the PCI at the non-SOS versus SOS hospital will be made on a random basis (the electronic equivalent of a flip of a coin). Every effort will be made to have the same physician that would have performed the PCI procedure at the non-SOS hospital, perform the procedure at the SOS hospital. However, if, that physician is not available, one of the trained staff interventional cardiologists at the SOS hospital will do the procedure.

It is routine for several medical tests to be done prior to patients having a PCI. These tests include an electrocardiogram (ECG), exercise (treadmill) test and other routine blood tests. Each patient will also have undergone a diagnostic cardiac catheterization with coronary angiography (placement of catheters under local anesthesia, with injection of a special contrast agent (dye) into the coronary arteries under x-ray imaging), to determine the location and severity of any coronary narrowing. Information from these tests will be used to verify that the type of blockage you have is suitable for treatment by PCI, and to ensure you meet all the inclusion and exclusion conditions established for this study. If you decide to join and have signed this consent form, the PCI may be performed at the end of your diagnostic catheterization, either at the same (non-SOS) hospital or after transfer to a SOS hospital, as specified by the protocol assignment. The PCI procedure usually takes an additional 1 to 2 hours, using the same catheter insertion site.

Following the procedure, the catheters are removed, and patients usually remain in the hospital for an additional 24 hours. During that time, additional ECGs and blood tests will be obtained to document if there are any procedure-related complications (heart muscle damage [heart attack] or bleeding). Your physician and the research staff will submit details of your baseline medical condition, the PCI procedure, and your post-procedure health status, to the Harvard Clinical Research Institute (HCRI), the clinical research organization responsible for this study, using secure and confidential electronic data transmission.

Post procedure follow-up tests will consist of routine visits to your cardiologist at 1 month (30 days) and 12 months following the procedure, to document the status of your health after the PCI procedure. Routine ECGs or exercise testing may be performed if clinically necessary, and you will be asked about your exercise tolerance and any episodes of chest pain following the PCI procedure. These data will also be submitted to the Harvard Clinical Research Institute, using secure and confidential electronic data submission.

Should you develop any clinical problems (recurrent chest pain, heart attack, stroke, etc.) during the 12 months following the procedure or require readmission to the hospital, especially if you have a repeat cardiac catheterization or another PCI or a coronary bypass surgery (coronary artery bypass grafting, CABG) during that period, any coronary angiography films and medical data from the readmission or repeat procedures would also be submitted to the Harvard Clinical Research Institute.

CONFLICT OF INTEREST

The seven (7) non-SOS hospitals are funding this study. Your doctor who will be performing the PCI is on staff at the non-SOS hospital with privileges at the SOS hospital. The goal of this study is to show that PCI performed at a hospital without the capability of performing heart surgery is as safe and effective as PCI performed at a hospital with heart surgery on-site. The non-SOS hospital and doctor may gain financial benefit from your enrollment in the study if your PCI is performed at the non-SOS hospital especially if the goals of the study are met.

RISKS

As with all research studies, there are risks to participating in this study. The PCI procedure you will have is clinically necessary to manage your coronary artery disease, and carries small but real risks of major complications including heart attack, death, stroke, injury to vessels at the catheter introduction site, bleeding, or clotting of the stents [small hollow metal mesh devices placed inside your artery to keep it from narrowing]). Also there is a chance that myocardial ischemia

may happen again after a successful PCI procedure, due to progression of prior narrowing or the development of new coronary artery narrowing, requiring either another PCI or a bypass operation.

Those risks would apply to your clinically-indicated PCI procedure in any event. The main additional risk of participating in this study, is that the performance of PCI at a hospital without cardiac surgery on site (non-SOS) is not endorsed by either the existing Guidelines of the American Heart Association/American College of Cardiology, nor by the PCI Guidelines of the Department of Public Health of the Commonwealth of Massachusetts (except in the context of

participation in the current study). *Should a complication arise during PCI at a non-SOS hospital requires emergency surgical repair, this would require prompt ambulance transport to a collaborating hospital that offers cardiac surgery.* Although the incidence of such complications is low (roughly 1 in 1,000 procedures), and provisions have been made for prompt ambulance transport of patients requiring emergency surgery to a hospital offering such service, delays in providing needed emergency surgery can potentially result in heart attack or even death.

There may also be some incremental risk if you are randomized to be transferred to a SOS hospital for your PCI. This would include a small risk of bleeding or clotting at the catheter insertion site during transport to the SOS hospital, or a small risk of heart attack during transfer. On the other hand, this type of transfer to a SOS hospital is routine clinical practice outside of the current study.

FETAL RISK/BIRTH CONTROL

Women who are pregnant are not included in this study. If you are a woman of child-bearing age and might be eligible for the study, a negative pregnancy test would be required before participation, and effective means to prevent pregnancy during the course of the study would be recommended.

UNFORSEEABLE RISKS

There may be some unknown or unanticipated discomforts or risks in addition to those described above that are not known at this time. You will also sign a separate hospital informed consent form for the Percutaneous Coronary Intervention (PCI) which will detail the additional risks of that procedure, whether or not it is performed as part of the current study.

ALTERNATIVES

You do not have to participate in this study to receive treatment for your condition. If you do not participate, however, your PCI procedure would need to be performed at a hospital that offered cardiac surgery on-site (SOS). The procedure could still, however, be performed by the same physician who would have done the PCI at the local (non-SOS) hospital. Should you decide not to undergo a PCI at all, there are a number of alternatives available for the treatment of myocardial ischemia, ranging from various drugs, other non-medicinal and/or surgical therapies. Your study investigator will discuss with you the risks and benefits of alternative treatment and therapies.

BENEFITS

Performing PCI in a community hospital by a trained Cardiologist with the assistance of the local Primary care physician allows the patient to stay in the community setting and not have to travel away from family, friends, and other social networks.

NEW FINDINGS

You will be informed of any new findings concerning PCI without on site cardiac surgery that develop during the study, and that may affect your willingness to participate in this study. In addition, a Data and Safety Monitoring Board (DSMB) will periodically review the safety results of this study to monitor whether elective PCI without cardiac surgery on site (non-SOS) is not as safe as elective PCI with SOS. If there is any question about the safety of the study, the DSMB may recommend that enrollment be stopped at any time. Also, should there be information from other studies that clearly suggest a lack of safety, the DSMB will consider those data along with the results to date, to determine if enrollment in this study should continue.

COMPENSATION FOR INJURY

You and your insurance company are responsible for any costs related to your treatment that are considered standard of care. Standard of care costs are costs for tests, procedures, and interventions that would be medically necessary even if you do not participate in this study. You will be responsible for all patient-responsibility payments such as co-pays, deductibles and co-insurance.

In the event of injury related to participation in this research study, any medical treatment that is necessary will be provided to assist your recovery from the injury. This care does not imply any fault or wrong-doing on the part of the hospital participating in this study or the doctor(s) involved. The hospital participating in the study reserves the right to bill third party payers for services you receive for the injury and to make other decisions concerning payment in such instances. No compensation of this injury will be provided by the hospital for such injury. If you experience a side-effect or injury, and if emergency medical treatment is required, you must report it immediately to the study investigator. You do not give up any of your legal rights as a research subject by signing this form.

COSTS

There will be no charge to you for your participation in this study.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is voluntary. You may refuse to participate or you may withdraw at any time without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. If you have already undergone the PCI procedure per the assignment of SOS or non-SOS hospital per this study, however, we would strongly encourage the routine clinical follow-up visits at 1 and 12 months, with submission of the associated clinical data by your physician, so that the ongoing safety of the performed procedure can be ascertained.

The study investigator or Sponsor can stop your participation at any time without your consent for the following reasons: if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if it is discovered that you do not meet the study requirements, if the study is canceled, or for administrative reasons. If you withdraw voluntarily or are withdrawn by your study investigator, you may be asked to have laboratory tests and examinations your study investigator finds necessary for your safety.