

****FOR CCI USE ONLY****

Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Administrator: Lily Moy/WC

Consent Approval Date: 03/07/2011

Protocol Number: 2009P-000120

Study Approval Expiration Date: 02/13/2012



INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN MS, Kashaine Gray BS
PROTOCOL NUMBER: 2009P-000120

INTRODUCTION:

You are invited to take part in a research study called, Multi Center Combined Non-Invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography.

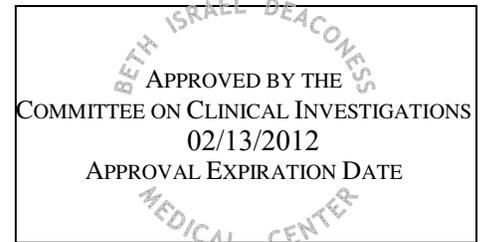
You are being asked to take part in this study because you have symptoms that may be related to your having blockage of your heart arteries. This research study involves having a non-invasive imaging study to get pictures of your heart arteries and another to determine if your heart muscle supplies enough blood to your heart when it is stressed. These tests will be performed using a CAT scan known as Multi Detector Computed Tomography or MDCT. We can include only people who choose to take part. Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study.

You should know that:

- Your participation is voluntary
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research
- You may leave the study at any time
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with your doctor or with Beth Israel Deaconess Medical Center

Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Dr. Roger Laham and is funded by Toshiba Medical Systems. The funding agency in this study, Toshiba, is paying Beth Israel Deaconess Medical Center to perform this research. Neither BIDMC nor Dr. Laham has any additional interests in this research project or in the funding agency.

WHY THIS STUDY IS BEING DONE

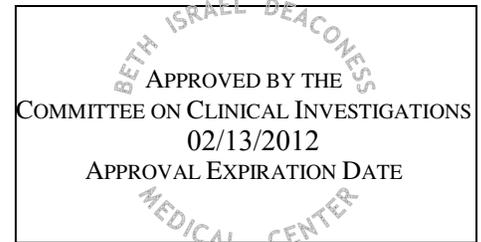
The purpose of this research study is to learn whether non-invasive medical testing is able to accurately diagnose coronary heart disease and measure blood flow to the heart. Coronary heart disease (CHD) is a narrowing of the small blood vessels that supply blood and oxygen to the heart and is usually caused by a condition called atherosclerosis, which occurs when fatty material and a substance called plaque build up on the walls of your arteries.

People with suspected coronary heart disease typically undergo coronary angiography to provide definitive information about the heart arteries and some form of stress testing (such as running on a treadmill) to tell whether the heart is getting enough blood flow. Coronary angiography (sometimes called heart catheterization) is an invasive X-ray examination of the blood vessels or chambers of the heart. A very small tube called a catheter is inserted into a blood vessel in your upper thigh (groin area) or arm. The tip of the tube is positioned either in the heart or at the beginning of the arteries supplying the heart, and a special fluid (called a contrast medium or dye) is injected. This fluid is visible by X-ray, and the pictures that are obtained are called angiograms.

In this study we hope that by using Computed Tomography, also called a CAT or CT scan, we can accurately diagnose your CHD. A CAT scan is a non-invasive test that uses special x-ray equipment as well as computers to produce multiple images or pictures of the inside of your body. In this study we also hope to determine if computed tomography stress testing using single photon tomography with radioisotopes (SPECT-MPI) will be as accurate as treadmill stress testing to tell whether the heart is getting enough blood flow. The SPECT-MPI is a non-invasive type of nuclear imaging test that uses a radioactive substance and a special camera to create 3 dimensional pictures of your organs.

At the end of this study, we hope to show that the MDCT angiography with perfusion in one test will be as accurate as the standard coronary angiography and the SPECT-MPI stress test in diagnosing CHD and measuring the blood flow to the heart. We also hope that this study will show the potential to save

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



patients the risks associated with the invasive tests used in the diagnosis of CHD, the costs of multiple screening tests, and finally we hope that this technique will potentially decrease a patient's exposure to radiation.

All of the medications and medical devices that are used in the study have been approved by the Food and Drug Administration (FDA). The medications used in this study are all currently used for stress testing. The medications such as Adenosine have already been tested and are currently used in SPECT scanning using standard gamma cameras; however, stress tests done when injecting adenosine into your vein to stress your heart have not been performed using the CAT scanner (MDCT) as the instrument to collect the pictures of your heart. Using the CT scanner to perform stress testing is the main portion of this research study. Although we have used CT scanning to evaluate arteries for atherosclerosis, we have not used this non-invasive method to determine if it is effective for measuring blood flow to the heart with arteries that are partially blocked.

The blood taken is to determine that your kidneys are functioning well, and that your cholesterol level and blood markers are consistent with those associated with patients who have atherosclerosis.

WHO WILL PARTICIPATE IN THE STUDY

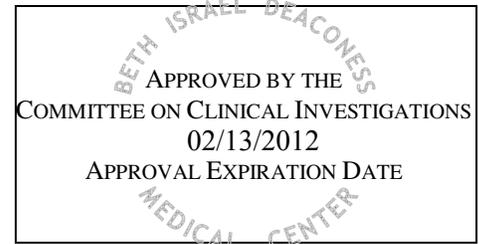
People aged 45-84 years, who are suspected of having coronary artery disease based on clinical history and results of stress testing, usually perfusion treadmill test (SPECT-MPI), and are scheduled for coronary angiography as part of their standard clinical care, may join.

Approximately 50 people will take part in this study at Beth Israel Deaconess Medical Center. A total of 400 people will take part in this study at all study sites. Prior to the initiation of the study there will be a run in phase for the purposes of personnel training of equipment use, data transfer, and analysis. Each site will include up to 3 roll in participants for a total of 45 participants at all sites. The data obtained from these participants will not be added to study analysis, but will be added to the study registry. You will be informed by the study doctor if you are in the run in phase.

WHAT WILL HAPPEN DURING THE STUDY

The research portion of the study includes the CT angiogram of your heart arteries, the CT perfusion stress study by injecting a drug that is approved for use, and another injection of contrast dye, drawing blood from your arm vein at the time that you have your CT angiogram to test for blood cholesterol and blood markers associated with atherosclerosis and the analysis of these studies. All other studies are

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasiliios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



those used to evaluate your symptoms and determine if you have disease in your heart arteries. If you agree to be in this study, we will ask you to do the following things:

1. **Screening Procedures:** Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study your medical record will be reviewed by study staff to collect information about your heart and your health. Your clinically indicated coronary angiogram will not be delayed as a result of participating in this research study.
2. **Research procedures:** Prior to undergoing your clinically-indicated catheter coronary angiography exam scheduled by your referring physician, study participants will be required to take part in 1-2 study visits. Before you can have the CT scan, we need to make sure your kidneys are working well and to examine your cholesterol and other markers of heart disease. A blood sample (about 3 tablespoons) will be taken from a vein in your arm.

These study visits will include:

- One single photon emission computed tomography myocardial perfusion (SPECT-MPI) study. This test will be compared to the standard treadmill perfusion test and your conventional coronary angiogram. If you have had a treadmill perfusion test within 6 months, you will not have to take this test.
- One multidetector computed tomography (MDCT) with an MDCTA-perfusion study. A multi-detector computed tomography to be compared to conventional coronary artery angiography to detect and evaluate significant coronary artery disease.

SPECT Study

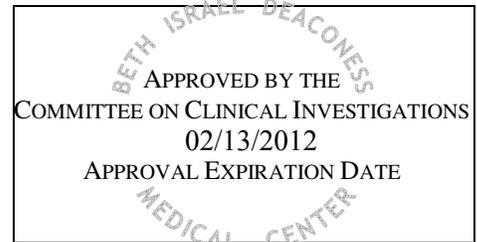
This test helps to determine which parts of your heart are healthy and functioning normally and which are not. This test is a standard clinical test that includes two portions: a rest and a stress portion. The stress portion can be done during exercise or with medications used routinely for this purpose. If you have had this test done within 6 months of joining our study, you will not be asked to repeat it.

Rest Portion of a SPECT Study:

You will receive a radiotracer injection in your arm. This is a radioactive substance that will



SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



help get better images (pictures) of your heart. 30-45 minutes after the injection, your heart will be scanned for about 15 minutes with a gamma camera.

Stress Portion of SPECT Study:

You will walk on a treadmill, while walking on the treadmill the speed and/or hill will increase every 3 minutes. A radiotracer injection (radioactive substance given to get better heart pictures) will be given in your arm while you are walking. You will be asked to continue to walk for 1-2 minutes after the injection. Your heart rate, blood pressure, and heart rhythm will be monitored. If you are unable to walk on a treadmill, an alternative stress test (pharmacological) in which the one of the following drugs: Adenosine, dipyridomole (Persantine) or regadenoson (Lexiscan) will be given to you. These drugs enlarge the vessels of your heart and increase your heart rate, similar to your body's natural response to exercise. These medications are routinely given in an IV line over 4-6 minutes per a standard stress protocol. A radiotracer injection will be given in your arm during or following the medication infusion (timing depends on which drug is given). Your heart rate, blood pressure and heart rhythm will be monitored during the study. 15-30 minutes after the treadmill test or after you received the pharmacological stress test , your heart will be scanned a second time for about 15 minutes with a gamma camera.

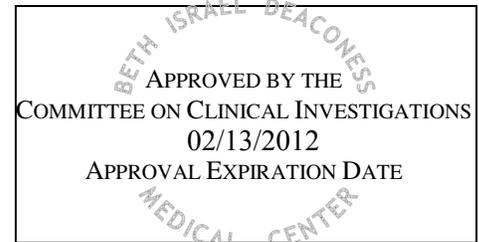
Computed Tomography (CT) study (also known as MDCT):

You will have a CT scan of the heart using contrast and adenosine. Adenosine is used to widen your arteries to see if there is enough blood flow to the heart and is commonly used in cardiac stress testing. It will be used for stress testing during your CT scan.

Before the scan begins, the CT staff will insert two intravenous (IV) catheters into your arm in order to inject contrast and adenosine. The CT scan uses radiation and will produce an image in three dimensions. During the test you will lie on your back on a padded table. A strap will be placed across your body to prevent movement so that the CT scan will be clear. The table will slide into a large, donut-shaped machine. An x-ray tube will slowly move around your body, taking many pictures from all directions. Prior to and after your CT scan, you will be given fluids through your intravenous catheter.

- During your CT scan, you will receive intravenous adenosine for about 5-6 minutes.
- You will be asked to hold your breath for about 10-15 seconds.
- Your blood pressure and heart function will be watched by a study doctor using an

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



- electrocardiogram (ECG) before, during, and after testing.
- The CT scan will last approximately 1 hour and the entire visit can last about 2.5 hours.

Note: Patients may receive an oral and/or intravenous dose of metoprolol up to one hour prior to the MDCT. If the Body Mass Index (BMI) <30 and the heart rate is >60 beats per minute, 75mg of metoprolol will be given orally and if the BMI ≥30 and the heart rate is > 60 beats per minute, 150 mg of metoprolol will be given orally. The Body Mass Index (BMI) is a measurement which compares a person's weight and height and then according to a BMI chart indicates a healthy body weight. If the HR remains >60 beats per minute at the scan acquisition then, intravenous metoprolol 2.5 - 5 mg every 5 minutes will be administered to achieve a heart rate between 50-70 beats per minute as blood pressure tolerates under the supervision of a physician. Patients with systolic blood pressure > 110 will receive a fast acting -short lasting nitrate (nitroglycerin or isosorbide dinitrate) sublingually (under the tongue)

3. Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called "monitoring" or "follow-up" procedures. For this research study, the monitoring/follow-up procedures include:

Following the SPECT scan, CT scan and angiogram you will be asked to fill out a questionnaire asking your impressions of the different imaging procedures.

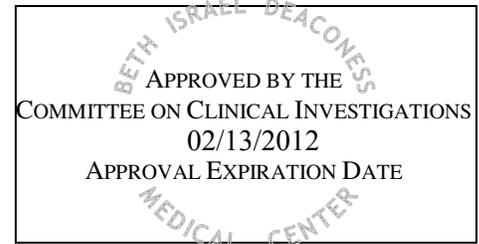
You will receive a phone call after 7 days, 30 days, 6 months, 1 year and 2 years after your MDCT study to ask if you have had chest pain, shortness of breath or any procedures related to your present symptoms or heart. The study allows for this follow up to also be done by a clinic visit or mailing; although at BIDMC follow up will be done by telephone contact. .

HOW LONG WILL THE STUDY LAST

Each study participant will be required to take part in a maximum of three study visits which will include:

- Taking about 3 tablespoons of blood from an arm vein.
- A Single Photon Emission Computed Tomography (SPECT) study (if a clinical SPECT study was performed 60 days prior to patient enrollment the SPECT study will not be repeated),
- a Multidetector Computed Tomography (MDCT) study,

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



- Clinically indicated catheterization.

Participation in this study will end after 2 years.

POSSIBLE RISKS, SIDE EFFECTS, AND DISCOMFORTS

RISKS OF THE RESEARCH STUDY

The radiation exposure risk from the angioplasty procedure involving fluoroscopy that is not part of this research protocol but is part of your clinical care is addressed in the consent form for that procedure. The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care. This research study involves exposure to radiation from the CT and SPECT sessions. The amount of radiation exposure that you will receive from these procedures is equivalent to a uniform whole body exposure of 2.8rem. This is equivalent to 56 % of the annual radiation exposure limit allowed for a radiation worker such as the technologist performing your SPECT scan. The risk from radiation exposure of this magnitude is considered to be comparable to other every day risks.

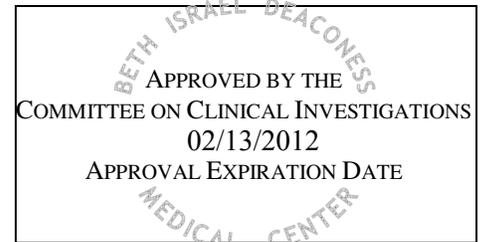
SPECT Study

- SPECT imaging is a routine clinical diagnostic procedure. The major source of discomfort is the need to lie still on a supine position for a relatively short time (12-15 minutes for each rest and stress images).

CT Contrast

- Reactions to the contrast agent (contrast dye) are uncommon and occur in less than 1 in 1000 people
- These reactions can range from mild itching and hives, to serious reactions including difficulty breathing and anaphylactic shock (low blood pressure and severe problems with breathing). Anaphylactic shock can result in death.
- To minimize this risk, you will not be allowed to join this study if you have a known allergy to CT contrast.
- In the event you have an allergic reaction to CT contrast, a physician will be present to give you medical treatment

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



- There is also a small risk of kidney damage from the contrast agent. Such damage is also rare and is usually, but not always, reversible. You will not be allowed to have a CT with contrast if your kidney function is impaired.

Adenosine

Adenosine is a very short acting drug and most of the side effects go away within 1-2 minutes after the infusion is turned off. In preparation for adenosine it is important for you to know that you are not allowed to eat or drink anything for four hours prior to the procedure. The side effects include flushing (44%), chest discomfort (40%), urge to breathe deeply (28%), headache (18%), throat, neck or jaw discomfort (15%), gastrointestinal discomfort (13%), and lightheadedness or dizziness (12%). Less common side effects include arm or hand discomfort (4%), temporary ECG abnormalities (3%), tingling of the limbs, hands and feet (2%), low blood pressure (2%), and nervousness (2%). Heart attacks, life-threatening abnormal heart rhythms and death have been reported in very rare instances (<1%).

Dipyridamole

The side effects of dipyridamole (Persantine) are as follows:

Worsening of chest pain (20%) hypotension (5%), hypertension (2%), blood pressure fluctuations (2%), ECG abnormalities 5% to 8%, pain (3%), increased heart rate(3%), dizziness (12%), headache (12%), flushing (3%), fatigue (1%), nausea (5%), paresthesia (numbness or tingling) (1%), dyspnea (shortness of breath)(3%)

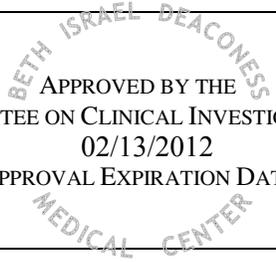
Regadenoson

The side effects of regadenoson (Lexiscan) are as follows:

Increased heart rate (22%), flushing (16%), extra heart beats(14%), chest discomfort (13%), ECG abnormalities (12%), headache (26%), shortness of breath (28%), premature atrial heart beats (7%), systolic blood pressure decreased >35 mm Hg (7%), delayed conduction of heart beats in the upper(atria) (3%) and lower chambers of the heart (ventricles) (6%) diastolic blood pressure decreased >25 mm Hg (4%), dizziness (8%), nausea (6%), abdominal discomfort (5%), abnormal taste (5%) ,feeling hot (5%)

Metoprolol

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120

 <p>APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS 02/13/2012 APPROVAL EXPIRATION DATE</p>

Metoprolol may cause low heart rates, low blood pressure, dizziness, breathing problems, or an allergic reaction. You will be observed for any of these effects. If you have any history of lung problems or asthma, please let the study personnel know.

Fast acting- short lasting nitrate

Nitroglycerin and Isosorbide Dinitrate can cause low blood pressure(hypotension). Other known side effects include headache (most common; 50% to 63%), lightheadedness (6%), syncope (4%), dizziness. Allergic reactions, cardiovascular collapse (cardiac arrest), exfoliative dermatitis (widespread scaling of skin often with itching and redness), methemoglobinemia (abnormal buildup of hemoglobin in the blood) (rare) overdose, pallor, palpitation, rash, rebound hypertension, restlessness, shock, vertigo, weakness reported in extremely very rare instances (<1%). Isosorbide dinitrate has similar effects and side effects as nitroglycerin. The study doctor will decide whether or not one of these drugs are given depending upon your blood pressure at the time of the study ,your cardiac history and any known intolerance.

Patients who take medications for erectile dysfunction (such as Viagra, Cialis or Levitra) must report this to the study doctor or nurse. Use of nitrates with these medications can cause very low blood pressure and/or fainting. There must be a 24 to 48 hour period between taking these medications and nitrates to avoid serious side-effects.

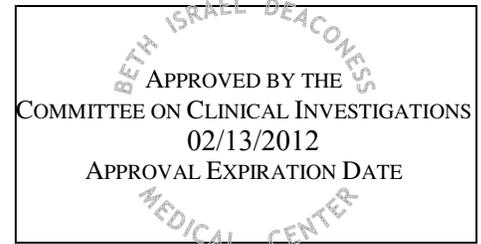
Intravenous (IV) Insertion

The CTA staff or research coordinator will use a needle to insert two intravenous catheters (one each arm) in order to inject contrast and adenosine. There is a risk of pain at the site where the needle is placed. You are also at risk for infection, bruising, swelling and bleeding at the site. When any IV medicine is given, there is always a chance that needle inserted in a vein may infiltrate (become blocked or puncture the wall of the vein) causing temporary swelling, bruising, and or pain. Should this occur, the study nurse will remove the IV and insert a new needle into another vein. To reduce these risks, the CT staff or research coordinator will follow standard procedures for the safe insertion of IV catheters.

Blood Sample

Taking blood may cause pain, bleeding or bruising where the needle is place. In rare cases, it may result in fainting. There is a small risk of infection.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



Pregnancy

Exposure to radiation can harm a fetus. If you are pregnant or nursing, you will not be allowed to join this research study. If you are a female who is able to become pregnant, you will be given a pregnancy test before your CT scan. The results of that test must be negative for you to continue in the study.

Other Risks

There may be side effects and discomforts that are not yet known.

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

LOSS OF CONFIDENTIALITY

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. However, if your participation becomes known, it could create a problem or hardship for you depending upon the type of information disclosed.

PSYCHOLOGICAL STRESS

There may be some temporary psychological stress during the course of this study due to the short term side effects from the medications that will be used. These may include flushing, chest pain, shortness of breath, fast heart rate, dizziness and headache. The study doctor and nurse will monitor you closely for these reactions and provide support during this time.

You may also feel some stress during the CT Scan since you will be in a confined space for a short period of time with hands raised over your head. The study team will be there to assist you during this time.

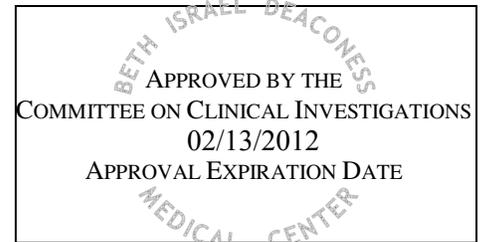
POSSIBLE BENEFITS

There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. You can choose to decline participation in this study and receive standard therapy for you condition.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with your doctor or with Beth Israel Deaconess Medical Center. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

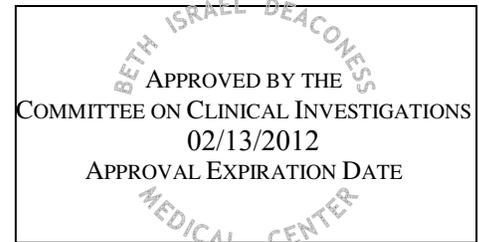
You will not be charged for any imaging studies, blood tests, or medications that are part of this research study. However, you and your insurance company will be charged for other tests, medicines or procedures of this study that are considered standard treatment for your medical condition.

PAYMENTS TO YOU:

You will receive a parking voucher to cover parking expenses at the BIDMC. You will also receive \$50 per visit for a maximum of \$100.

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than \$600 or more in one calendar year for taking part in one or more research studies at BIDMC. Questions about your own tax status should be referred to your personal tax advisor.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study, you should contact the Investigator at the number provided under the section “Who to Call if You Have Questions” in this form. You will be offered the necessary care to treat your injury. We reserve the right to bill your insurance company or the sponsor, if appropriate, for the care you get for the injury. We will try to get these costs paid for, but you may be responsible for some of them. You may be responsible for all co-payments and deductibles required under your insurance. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

CONFIDENTIALITY

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA), other federal and state regulatory agencies, the Central Data Safety Monitoring Board, other hospitals in the study, company sponsors of the Study, other accreditation agencies, the Committee on Clinical Investigations and the Human Subjects Protection Office of the Beth Israel Deaconess Medical Center with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

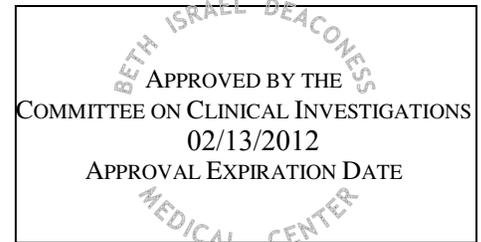
As part of this study, we will be collecting and sharing information about you with others. Please review this section carefully as it contains information about the federal privacy rules and the use of your information.

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists such as; *your medical records and laboratory tests* as well as any new information generated as part of this study through such as the MDCTA-MPI test we ask you to undergo. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL USE YOUR PROTECTED HEALTH INFORMATION

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



Your Protected Health Information may be shared with investigators listed on this consent form as well as the supporting research team [i.e. research assistants, statisticians, data managers, laboratory personnel, administrative assistants]. Your Protected Health Information may also be shared with the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center as it is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

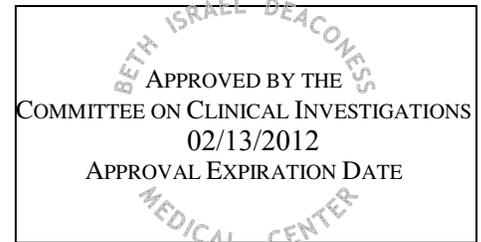
- The funding source of this study, Toshiba Medical Systems, and their clinical research organizations
- The other research collaborators at other hospitals and medical centers taking part in this study not affiliated with BIDMC are: Johns Hopkins Hospital, Joao A. Limam MD; Bayview Medical Center, Edward Shapiro, MD; InCore Heart Center, Sao Paulo, Brazil, Carlos Rochitte; Leiden, NL, Albert DeRoos; Mont Elizabeth, Singapor, John Hoe, MD; Iwata University, JP, Kunihiro Yoshioka, MD; Toronto General Hospital, Canada, Narinder Paul, MD; Charite, Humbolt U, Berlin, Marc Dewey, MD.
- Centralized data collectors: Johns Hopkins and Brigham and Women’s Hospitals.
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], and the Office for Human Research Protections [OHRP].
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study

Those who receive your Protected Health Information may make further disclosures to others. If they do, your information may no longer be covered by the federal privacy regulations.

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. We also shall use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120



NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Roger Laham, MD, Principal Investigator; 330 Brookline Ave., TCC-7, Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter.

REFUSAL TO SIGN

If you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

NOTICE OF PRIVACY PRACTICES

In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

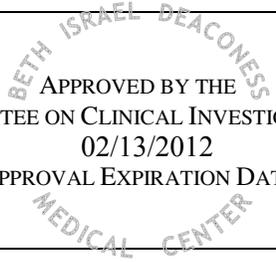
WHOM TO CALL IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions about this research or experience any problems, you should contact Dr. Roger Laham at [617] 667-8800 or Dr. Melvin Clouse at [617] 754-2529.

You may contact the Human Subjects Protection Office at [617] 667-0469 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator’s research staff and can also assist with questions relating to your rights as a



SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: Multi Center Combined Non-invasive Coronary Angiography and Myocardial Perfusion Imaging using 320-Detector Computed Tomography
PRINCIPAL INVESTIGATOR: Roger Laham, MD
CO-INVESTIGATORS: Melvin E. Clouse, MD, Ernest Gervino, MD, Gerald K. Kolodny, MD, Faisal Khosa, MD, Sheryar Sarwar, Vasilios Raptopoulos, MD, Atif Niaz Khan, Thomas Hauser, MD, David Leeman, MD, Donald E Cutlip, MD, Michael Gibson, MD, Duane Pinto, MD, Samuel Shubrooks, MD, Kalon Ho, MD, Michael Levy, MD, Jean Touchan, MD, Jenifer Kaufman RN,MS, Kashaine Gray BS
PROTOCOL #: 2009P-000120

 APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS 02/13/2012 APPROVAL EXPIRATION DATE
--

participant in research, which may include questions, concerns or complaints about your participation in the study.

ICF REVISION DATES:

- July 21, 2009
- November 3,2009 IRB requested radiation language
- November 23,2009 Sponsor amendment (8/13/09)
- January 11,2010 IRB requested modifications
- 02/07/2011 - Research Team Update
- 02/28/2011 – IRB requested modifications

