Official Title:	A Single Center Study of Perivascular Coronary Inflammation in Patients With Myocardial Ischemia or Infarction With Non-Obstructive Coronary Arteries
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NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	**A SINGLE CENTER STUDY OF PERIVASCULAR CORONARY INFLAMMATION IN PATIENTS WITH MYOCARDIAL ISCHEMIA OR INFARCTION WITH NON-OBSTRUCTIVE CORONARY ARTERIES** **Study Number: s21-00764**
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to find out whether inflammation of blood vessels as seen on a heart scan can help to find the cause of heart damage, chest pain, or abnormal stress test results in men and women with “open arteries” (without major blockages).

You are being asked to participate in this study because you had symptoms that might be from the heart, with or without an abnormal cardiac stress test, or had heart damage that was identified by a blood test and/or electrocardiogram, and your doctor ordered a cardiac catheterization (also called a “cath”) with a coronary angiogram as part of your routine care.

3. How long will I be in the study? How many other people will be in the study?

Your participation in the study will last 1 year and will include a single visit for a CT scan (also known as a “CAT” scan) of the heart. A total of 32 individuals will take part in this pilot study.

4. What will I be asked to do in the study?

Screening Visit

You are being asked to participate in this study because you had symptoms that might be from the heart, had an abnormal cardiac stress test, or had heart damage that was identified by a blood test and/or electrocardiogram, and your doctor ordered a cardiac catheterization (also called a "cath" or "angiogram") as part of your routine care. We are asking you to read and sign this consent for participation in the research study. No research procedures will be done until after you have read and signed this consent form and the study team checks that you are eligible to participate in the study.

If more than half of any major heart artery is blocked, you will ***not*** be eligible to have the research measurements described below.

CT Scan Visit

If your arteries are at least halfway open and are eligible, you will be scheduled for a CT scan (also known as a "CAT" scan) of the heart, at a separate visit. The heart CT scan will check whether there is inflammation surrounding the major blood vessels of the heart. It will check whether there is plaque in the vessels of the heart. This same test is also regularly ordered by doctors to evaluate the heart in routine clinical care.

Results from this test will be available to your doctor following the scan, and may (or may not) be used in decisions about your treatment, as your doctor sees fit. You and your doctor will have access to the results of the test showing whether you have heart artery plaque, but you will not have access to the research testing such as the inflammation measurement.

Prior to performing the heart CT scan (also known as a coronary CT angiogram, or CCTA), an intravenous (IV) catheter (hollow tube) will be inserted into your arm. Once the IV is inserted, if your heart rate is fast, a medication called a beta-blocker (usually metoprolol) will be given through the IV to temporarily slow your heart rate. You will lie on the table of the CT scanner and a nitroglycerin tablet will be placed underneath your tongue to relax the blood vessels of the heart. Metoprolol and nitroglycerin, short-acting Food and Drug Administration (FDA)-approved medications, are routinely administered during CT scans for the purposes of clinical care. In this research study, their use is considered 'off-label' because they are not indicated for optimization prior to CCTA. If you are unable to take metoprolol, another FDA-approved medication, diltiazem, may be used as an alternative. We will be using these drugs in the same manner (and at the same doses) in which they are used during clinical care. Contrast "dye" will be given though the IV in your arm immediately before the CT scan is acquired. This medication is required to view the blood vessels of the heart. The CT scan takes approximately 30 seconds to acquire.

Any identifiable information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

The following are risks and discomforts that you may experience during your participation in this research study. In addition to these risks, the research may involve other risks that we cannot currently predict:

IV Placement:
Risks of inserting an IV catheter include pain, bruising, bleeding and in rare cases, infection. The IV will be removed after the CT scan of the heart is complete.

Pre-Medication Prior to CT Scan:
Medications are usually needed to relax the blood vessels of the heart (nitroglycerin) and slow the heart rate (beta-blockers, usually metoprolol, or alternatively, diltiazem) for the best possible CT scan images. Side effects of nitroglycerin can include low blood pressure, flushing, dizziness and headache. Nitroglycerin is very short acting and side effects usually last ≤10 minutes. Medications to slow the heart rate, such as metoprolol, can cause very slow heart rates, low blood pressure, dizziness, fatigue, and wheezing in some patients. If either of these medications is felt to be unsafe, it will not be given prior to the CT scan.

CT scan of the heart:
During this study, you will have exposure to radiation from the CT scan as it takes pictures of the heart. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be approximately 8.6 mSv, which is equivalent to roughly 3 times the yearly natural background of radiation in the US (3 mSv). The use of radiation may involve a low risk of cancer and is required to obtain the desired research information. Pregnant women cannot be exposed to radiation. Women must have a negative pregnancy test before they can have an CT scan.

In order to better see internal structures of your body during the imaging study, there is the injection of contrast media ("dye"). Infrequently, the needle (catheter) may slip out of the vein. The injected contrast media goes into the tissues and causes local pain. This is usually treated with appropriate compresses.

Some systemic reaction may occur, such as a metallic taste, nausea, vomiting, and hives. This is usually limited. Very infrequently, there is difficulty in breathing, low blood pressure and dizziness that requires appropriate treatment. Severe reactions are extremely rare where death has occurred. If you have allergies, the possibility of reaction is higher than patient a without allergies. If applicable, in consultation with your doctor, it may be needed to have pre medication to decrease the possibility of these complications.

Patients who have bad kidney function are at risk for worsening their kidney function. A simple blood test will identify the patient at risk for kidney damage. Alternative imaging studies may be indicated. If you are a diabetic on oral medication, it is recommended that you stop taking the medication for the two days after the contrast injection.

This medication can cause a serious allergic reaction in <1% of patients. If you previously had an allergic reaction to contrast ("dye") you will not be eligible to participate in this study.

6. Can I be in the study if I am pregnant or breastfeeding?

Because taking part in this study may harm an embryo or fetus, if you are currently pregnant, you will not be able participate in the study. If you are a woman of childbearing age and are uncertain whether or not you are pregnant, you will need to have a pregnancy test done before the scan.

7. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

Incidental (unexpected) findings:

The CT scan is focused on your heart, but some parts of the lungs and chest are included in the scan. It is possible the CT scan may find an unexpected result (incidental finding) that is or is not related to the heart. Such a result may or may not be important to your health. Each scan is reviewed by a licensed radiologist (imaging doctor). Any unexpected findings that may be important to your health will be included in the report of the test provided to you and your doctors. If unexpected findings are identified, they will be disclosed to you and will also be added to your medical record. In the event there are unexpected findings, you are advised to speak with your doctor about any further care that is required. Your doctor may recommend additional testing, such as follow up CT scans. Incidental findings may lead to diagnoses that would not have been made without the CT scan, but may also cause additional stress or anxiety. There is no guarantee that all incidental findings may be found through this research study.

8. What are the possible benefits of the study?

You are not expected to get any direct benefit from being in this research study. However, others with chest pain or heart damage and open arteries may benefit in the future from what we learn in this study. You may feel good about contributing to medical knowledge, and helping researchers make discoveries that might help people in the future.

The limited results of the CT scan will be available to your physicians. We hope that any knowledge gained will be of benefit to you. We cannot be certain that the tests will give you or your doctor useful information.

9. What other choices do I have if I do not participate?

You do not have to participate in this study to receive ongoing care for your condition. You may discuss alternatives with your personal physician. The choice you make will not have any impact on your cardiac care.

10. Will I be paid for being in this study?

You may be reimbursed up to $50 for travel to or parking at the medical center for the research CT. In order to be paid, you must give the receipts to the study staff.

11. Will I have to pay for anything?

The CT scan of the heart will be paid for by the study. You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

14. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- H+H personnel responsible for the support or oversight of the study at Bellevue Hospital

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health.

This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?
The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately.

As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

The research-related information that will be available to you immediately are as follows:

- ***Results that may be placed in the medical record:*** *Standard heart CT scan clinical report, written by a radiologist.*

Access to research-related information within your EMR can be found through NYU Langone Health's patient portal, MyChart.

In this study, some research-related information will never be made available to you in your EMR. This information will not be accessible in your EMR because *the information is specific to this research project and is not part of clinical care.*

- ***Results that will not be placed in the medical record:*** *Investigational Measurements of vessel inflammation based on research investigational analysis of the CT Scan images.*

17. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

18. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent of Non-English Speaking Subjects Using the "Short Form" in Subject's Spoken Language

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date