Effects of Sublingual and Transdermal Administration of Nitroglycerin for Coronary CT Angiography on Image Quality

NCT#: NCT02961946

Consent Form

February 23, 2017

Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: August 2016

Protocol Title: Effects of sublingual and transdermal administration of Nitroglycerin for Coronary CT-Angiography on image quality

Principal Investigator:

Site Principal Investigator:

Description of Subject Population: Adults who are scheduled for coronary CT Angiography

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Why is this research study being done?

The purpose of this research study is to evaluate the image quality of the CT examination of your heart. We will give you a medication (Nitroglycerin) that will widen the vessels of your heart. There are different ways of giving you this medication. This medication is routinely given for the CT examination of your heart. It is a safe drug with few contraindications. If you don't have a contraindication to this medication, you will be randomly placed in one of three groups. You will receive this medication as either a spray, a tablet under your tongue, or a patch on your skin. This study does not affect the medical decisions made by the doctor who has been treating you. We plan to investigate 210 patients in this study.

How long will I take part in this research study?

You are scheduled for a CT examination of your heart. There is no additional visit to MGH necessary for this research study. The complete CT examination of your heart will take around 1.5 hours.

What will happen in this research study?

When you decide you want to take part in this study and we verify that you have no contraindications to Nitroglycerin, we will ask you to sign this consent form. After signing the form, you will be placed in one of 3 groups which decides how we give you the medication. You will receive this medication as either a spray, a tablet under your tongue, or a patch on your skin.

An electrocardiogram (ECG) will monitor your heart during the procedure. Blood pressure and heart rate will be measured before and after the CT examination.
After the scan is finished, we make sure that you do not have any reactions to the drugs we gave you. After finishing the CT examination we will remove the skin patch if you have received it before. No treatment is necessary if you have received the spray or tablet.

After the CT examination we would like to ask you to fill out a survey. This includes questions about discomfort during the study.

What are the risks and possible discomforts from being in this research study?

The medication is routinely given to improve the image quality. It has a few contra-indications which we go check with you before the examination. There is a small risk of allergic reaction and low blood pressure.

What are the possible benefits from being in this research study?

The results of this study does not influence your further treatment. Our aim is to optimize the process of the CT examination of the heart.

What other treatments or procedures are available for my condition?

Nitroglycerin is routinely given before the CT examination of the heart. We will give you a standard Nitroglycerin tablet under the tongue if you do not want to take part in this research

study. The only time we wouldn't give patient like you a Nitroglycerin tablet before a CT of your heart is if you have a medical condition that makes it unsafe.

Taking part is totally voluntary. You can withdraw your consent and stop taking part in the study at any time without affecting your present or future care at the Massachusetts General Hospital.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

No.

What will I have to pay for if I take part in this research study?

There will be no cost to you for taking part in this research study.
Costs for your regular, ongoing medical care, which is not a part of this study, will be billed to you or to your health insurance company in the usual way.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

XXX is the person in charge of this research study. You can call his office at XXX M-F 9 am - 5 pm.

If you have questions about the scheduling of appointments or study visits, call XXX.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the

sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

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

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter | Date | Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

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 | Date | Time (optional)

Consent Form Version: 02/23/2017