TONOMETRY STATION CONSENT FORM

Basic Information

Title of Project: Aortic stiffness, wave reflection, and cerebrovascular flow pulsatility: relations with brain small vessel disease and cognitive function in a middle-aged cohort

IRB Number: H-43774

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Study Phone Number: (617) 358-1304

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a current participant in the Framingham Heart Study. We are doing the research to allow us to evaluate the relationship between cardiac risk factors, arterial stiffening and the development of cardiovascular disease. If you agree, you will receive two tests that noninvasively examine your heart and blood vessels' structure and function. These tests should not take more than 30 minutes to complete. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are a loss of confidentiality. You will find more information about risks later in this form.

Purpose

The aorta stiffens markedly with age, particularly during midlife, resulting in high blood pressure, reduced pumping efficiency of the heart, and damage to the small blood vessels in the brain. The high prevalence of aortic stiffening as we grow older, particularly in women and in those affected by obesity and diabetes, contributes to accelerated brain aging, memory loss, and development of Alzheimer's disease and related dementias. We propose to study mechanisms that link aortic stiffness to damage in small vessels in the brain.

What Will Happen in This Research Study

You will be asked to lay in a supine (reclined) position for 5 minutes. You will then receive the following tests:

Blood pressure

The sonographers will carefully measure your blood pressure while listening with headphones.

Arterial tonometry

The sonographer will hold a flat pressure-sensing device (the tonometer) against the superficial pulses in your elbow, wrist, top of your leg, and neck for approximately a minute at each of these four sites. We will also attach a watch-like fitness tracker to your upper arm in order to detect a pulse waveform. These waveforms allow us to assess blood vessel stiffness.

The sonographer will also acquire an ultrasound view of blood flow in the aorta (the large artery carrying blood flow from the base of your heart), the carotid arteries (in your neck) and the middle cerebral arteries (in your head behind the thin bone in your temple) as part of the tonometry evaluation.

The Arterial Tonometry Test results are solely used for research purposes. They are not used in clinical practice or to guide medical decisions. For this reason, we will not be sending the results to your physician. However, we might see something that could be important to your health. If we do, we will ask you if you want us to explain what we noticed. If you would like, we will also tell your doctor. You or your doctor should not rely on the research measurements to make any diagnosis, treatment, or health planning decisions. If you or your doctor decides that follow-up tests and treatments are necessary, then you or your insurance will be billed for the costs.

How is the test performed?

Tonometry measurements are made by gently pressing the tip of flat pressure sensing device (the tonometer) against the superficial pulses in the arm, leg and neck for approximately a minute at each of four sites. This device records the pressure waveform that is associated with each pulse or heartbeat. Flow measurements are performed by using Doppler mode of a standard clinical ultrasound machine.

Next, the distance from the base of the neck to each of the pulse sites is measured.

You will be asked to lie quietly during this phase of the testing. There should be no discomfort associated with tonometry. Blood pressure cuff inflation may be uncomfortable for some. In addition, the ultrasound probe may cause mild to moderate discomfort on your chest when taking limited views of your heart. This test has been performed safely in thousands of research participants.

At a later date, using a computerized analysis, we will examine the shape of the pressure waveforms and calculate the speed at which pressure waves travel through the large arteries.

We will analyze the results of these tests in conjunction with other data collected from you as part of your participation in the Framingham Heart Study in order to study the relationship between cardiac risk factors, arterial stiffness, and cognitive health or disease in aging.

Risks and Discomforts

There is a risk to the confidentiality of your health information. We take special efforts to protect your health information, but there is a small chance of a data breach. The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

As noted above, there may be some discomfort during blood pressure cuff inflation and when we acquire limited ultrasound images of your heart.

Potential Benefits

You will receive no direct benefit from being in this study. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in this study may help the investigators develop treatments that limit damage to the small arteries and capillaries in the brain and prevent the severe consequential effects of arterial stiffness on brain structure, cognitive function, and the potential for Alzheimer's Disease and related dementias.

Costs

There are no costs to you for being in this research study.

Payment

You will not be paid for being in this study.

The research may lead to the development of drugs, tests, or procedures that might have commercial value. You will not get any money if products are developed from the research.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Maureen Valentino at (508) 872-6562. Also call if you need to report an injury while being in this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Subject: _____

Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described

To be completed by subject if personally signing

_____ _____
Signature of subject Date

To be completed by LAR if subject does not personally sign
I am providing consent on behalf of the subject.

_____ _____
Printed name of Legally Authorized Representative (LAR) Relationship to Subject

_____ _____
Signature of Legally Authorized Representative Date

Researcher: _____
Printed name of person conducting consent discussion

To be completed by researcher if subject personally signs
I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

To be completed by researcher if subject does not personally sign
I have personally explained the research to the above-named subject's Legally Authorized Representative and answered all questions. I believe that the Legally Authorized Representative understands what is involved in the study and freely agrees to have the subject participate.

_____ _____
Signature of person conducting consent discussion Date

BMC and BU Medical Campus IRB
IRB NUMBER: H-43774
IRB APPROVAL DATE: 05/24/2024