A Biomarker for Personalized Care in Post-stroke Spatial Neglect

NCT05256563

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U.S. Department of Veterans Affairs
Atlanta VA Health Care System

Informed Consent Template Version 7-1-20

Consent to be a Research Subject

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 45 people who are being studied at the Atlanta VA Health Care System.

Why is this study being done?

This study is being done to learn about stroke-related changes in the brain. You are being asked to be in this research study because you have had a stroke.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 1-2 in person study visits. The researchers will ask you to complete some behavioral assessments, and MRI scan and follow-up phone visits at 3 and 6 months after enrollment. If the MRI shows to be something you are not able to do due to medical reasons for example having a pacemaker, metal devices or other medical condition that impedes you from doing a magnetic resonance, or this is something you are not willing to do, you may still participate on other activities listed on this study (cognitive assessments).

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include claustrophobia or temporary hearing loss, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the RISKS section of this document.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand. Take time to consider this and talk about it with your family and friends.

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TITLE: A Biomarker for Personalized Care in Post-Stroke Spatial Neglect (SN)

PRINCIPAL INVESTIGATOR: [redacted]

SPONSOR'S NAME: Department of Veterans Affairs

PURPOSE:
You are being asked to volunteer in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

The purpose of this study is to attempt to speed up spatial neglect diagnosis, using the brain imaging that is always part of the first hours of stroke care. We will compare 4 methods to identify the special brain imaging features present in people with spatial neglect who respond to early rehabilitation, and who recover best at 3 and 6 months after stroke.

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

WHAT WILL I BE ASKED TO DO?:
If you agree to be in the study, the table below is an overview of the study activities. A full description of the activities follows the table.

PROCEDURES:

Study Visit	Activity	Time	Location
Consent	Informed Consent	Up to 1 hour	AVAHCS, EUH or Virtual Consenting
Baseline	Behavioral Assessment	Up to 1 hour	AVAHCS or EUH
Visit 1	MRI Scan (optional)	Up to 2 hours	WWHC or EUH
Visit 2	Behavioral Assessment	Up to 1 hour	Phone Visit
Visit 3	Behavioral Assessment	Up to 1 hour	Phone Visit

Consent: The study team will meet with you to review the Informed Consent. This visit will be conducted at the Atlanta VA Health Care System 1670 Clairmont Rd Decatur, GA 30033 or Emory University Hospital (EUH), 1364 Clifton Road, Atlanta, GA 30322. If you agree to be a participant, you will sign the consent form and a copy will be given to you prior enrollment.

Baseline Visit: After you have signed the informed consent and agree to study participation, you will be screened for the study enrollment by using the Montreal Cognitive Assessment, Geriatric Depression Scale, Behavioral Inattention Test and the Computerized Line Bisection test. If you meet the study inclusion and exclusion criteria, we will conduct behavioral assessments using measures including Barthel Index, the FONE-FIM, the Catherine Bergego Scale, Handeddness test, and other possible assessments such as the Florida Mini Mental Status Exam, 3D CAM and Social Responsiveness Scale.

Visit 1: MRI Scan your brain anatomical imaging will be recorded in a magnetic resonance machine. This visit will be conducted at Emory University, Center for Systems Imaging (CSI), Wesley Woods Health Center, 1841 Clifton Road NE, Atlanta, GA 30329 or Emory University Hospital (EUH), 1364 Clifton Road, Atlanta, GA 30322.

For the MRI, you lie down on a special table that slides inside the MRI scanner. You will be asked to stay very still during the scan. The space within the magnet is small. If you feel claustrophobic (uncomfortably confined), you can stop at any time. The MRI scanner makes loud repetitive tapping sounds when in use. You will be required to wear earplugs and protective ear coverings for hearing protection. You may be fitted for a bite bar in order to keep your head from moving during the scans.

Visit 2: We will conduct behavioral assessments through a phone visit with you and your caregiver using the Barthel Index, the Catherine Bergego Scale and the FONE-FIM at 3 months after Visit 1.

Visit 3: We will conduct our final behavioral assessments through a phone visit with you and your caregiver using the Barthel Index, the Catherine Bergego Scale and the FONE-FIM at 6 months after Visit 1.

RISKS:

The most common risks and discomforts expected in this study are related to the Magnetic Resonance Imaging (MRI). An MRI scan exposes you to strong magnetic fields. There is no evidence that this is directly harmful to you. Strong magnetic fields are capable of moving metal objects. Therefore, if you have any metal objects or fragments in your body, other than dental work, or you have a cardiac pacemaker, you must let us know so we can cancel this test.

The MRI scan is conducted like a CT scan but the area in which you lie is quite confining and some people experience claustrophobia, that is discomfort in enclosed spaces. If you are affected in this way, it will be important for you to let us know, as this could adversely affect the results of the study and would lead us to discontinue our research with you.

The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of individuals. You will be given hearing protection to reduce this risk. You may experience a temporary decrease in your hearing abilities accompanied by a ringing in the ears. This should stop within 48 hours from the time you were scanned. If this does not stop within 48 hours please contact **[redacted], Principal Investigator at [redacted].**

There may be side effects from the study procedures that are not known at this time. It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

BENEFITS:

There is no direct benefit to you from taking part in this study. However, this research study may help us learn new things that may help other people in the future.

COMPENSATION:

You will be compensated $75 for your time and effort including travel after your completion of the study. If you are not able to complete the entire study, compensation would be given as follows: $15 dollars for the baseline assessment and consenting, $50 dollars for the MRI and $10 for follow up visits over the phone. A check will be mailed to you 4 – 6 weeks after the conclusion of your participation.

You will get emergency medical care if you get injured from being in this study. Under Federal Law, you will qualify for follow-up treatment if the injury was related to the research study. You may or may not get further compensation if you are injured in this study. This rule would not apply if you do not follow study procedures. If you believe you have been injured by this research, you should contact **[redacted], Principal Investigator at [redacted]**

COSTS:
You will not be charged for any treatments or procedures that are part of this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.

The VA will provide the necessary medical treatment if you get injured from being in this study. This requirement does not apply to:

(1) Treatment for injuries due to non-compliance by a subject with study procedures;

Or

(2) Research conducted for VA under a contract with an individual or a non-VA institution.

If you believe you have been injured by this research, you should contact [redacted], Principal Investigator at [redacted].

ALTERNATIVES:
There are no alternative treatments and/or procedures to those offered in this research study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED:
We will keep information about you, including any research records we create, strictly confidential to the extent required by law.

We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files locked in a file cabinet in a private office. We will use [a study number*] rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results." People other than those doing this research study may have access to your medical and study records including:

- Sponsors, companies, or agencies paying for the study
- The Office for Human Research Protections

- The Government Accountability Office (GAO)
- The Inspector General
- Emory University
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.

If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP) and we will ask you to sign a form saying that you have received this notice.

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA):

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history and MRI scans.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Office of Human Research Protections (OHRP), the Inspector General, and the Government Accountability Office (GAO), and Emory University.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be

able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [redacted], 1670 Clairmont Rd NE Decatur, GA 30033 and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

RESULTS:
We will give you a copy of the brain MRI scan collected in the study, which you can share with others if you wish. If the researchers suspect that there is a finding of urgent medical importance in the MRI or on your cognitive assessments, then the Principal Investigator will inform you and the image(s) and/or results will be shared with your physician for further clinical evaluation.

IDENTIFIABLE PRIVATE INFORMATION OR IDENTFIABLE SPECIMENS:
Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

CONFLICT OF INTEREST:
No real or apparent conflict of interest

CONTACT PERSONS:
If you have any questions, concerns, or complaints about this study you can call a member of the study staff at [redacted].

If you have been harmed from being in this study call: [redacted]

If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:

The Research Compliance Officer at [redacted] or the Clinical Studies Center Manager at [redacted].

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at [redacted].

VOLUNTARY PARTICIPATION AND WITHDRAWAL:

The study doctors have the right to end your participation in this study for any of the following reasons: If it would be dangerous for you to continue, if you do not follow study procedures as directed by the study doctors, or if the sponsor decides to end the study.

Your participation is voluntary, and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. For your safety, however, you should consider the study doctor's advice about how to go off the study treatment.

The study doctor, investigator, or sponsor may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions.

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

RESEARCH PARTICIPANT'S SIGNATURE AND DATE:

_____
Research Participant's name

_____ _____
Research Participant's Signature Date