CUPID_EMS

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Cranial Ultrasound for Prehospital ICH Diagnosis (CUPID_EMS)
Informed Consent Form to Participate in Research
Dr. Aarti Sarwal, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is for Emergency Medical Service Personnel to detect strokes caused by brain bleeds en-route to the hospital through the use of cranial ultrasound. You are invited to be in this study because you were evaluated by EMS personnel for symptoms that could have been a stroke (even if the final diagnosis was stroke or not) making you eligible for participation. Your participation in this research will involve the completion of a cranial ultrasound, performed by EMS, en-route to the hospital and collection of medical information from prehospital care reports and emergency department (ED) evaluation.

Participation in this study will involve no more than minimal risk to you and will be on no direct benefit to you. There is a minimal possibility of an allergic reaction to the gel used to operate the ultrasound machine.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you chose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The principal investigator of this study is Dr Aarti Sarwal who can be reached at [redacted] for any questions, suggestions, or concerns regarding this study or you want to withdraw from the study. If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. If you are a family member representing a potential subject, you are invited to consider participation in the research study on the subject's behalf. If this is the case, whenever we refer to "you" herein, we are referring to the study subject. Research studies are designed to gain scientific knowledge that may help other people in the future. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is for EMS to detect strokes caused by brain bleed, intracranial hemorrhage (ICH) en-route to the hospital through the use of cranial ultrasound. Handheld ultrasound devices are very cost-effective and readily available for use by EMS, unlike CT scans which currently serve as the primary diagnostic tool for ICH and only available in ED. The use of cranial ultrasound could

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lead to a more rapid ICH diagnosis, allowing patients to receive appropriate care sooner, ultimately improving ICH outcomes. Cranial ultrasound is a non-invasive test that uses sound waves to take images of the brain and its blood flow. Ultrasound images can be used to visualize changes in brain caused by diseases like stroke and other pathologies. You or your family member was evaluated by EMS and stroke was one of the possible etiologies considered hence you were deemed eligible for this study. Participating in this study does not necessarily mean that you or your family member had a brain bleed, hemorrhage, or stroke.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We plan to enroll approximately 1000 patients into the study at all participating sites with principal investigator at Wake Forest Baptist Medical Center.

WHAT IS INVOLVED IN THE STUDY?

Ultrasound is a non-invasive test that does not require any needles, radiation exposure or patient discomfort. It is relatively inexpensive and is very portable. It has been used by radiologists and sonographers (ultrasound technologists) to image the human body for at least 50 years and has become one of the most widely used diagnostic tools in modern medicine. This test involves a handheld device with ultrasound probe placed directly on the hair and scalp. It sends out sound waves through the skull, these sounds get reflected by different parts of the brain and are caught by the transducer placed inside the probe. The captured sound waves are then processed to make images of brain. The results are displayed on the portable phone/tablet screen. A small amount of gel may be placed on the skin to allow ease of conduction of sound waves from the probe to the skull. Gentle wetting of the skin assures excellent transmission of ultrasound waves. This gel is hypoallergenic, non-sensitizing and does not stain clothing or irritate skin. No needles, contrast agents or dyes are involved in this test.

If you take part in this study, you will have the following tests and procedures:

Cranial ultrasound: The test will be done by the EMS during their evaluation in the ambulance when they determine that performing the test will not interfere with patient's care. The ultrasound probe will be placed on the scalp and will be used for visualizing the different areas of the brain. A small amount of gel may be applied to the skin to allow easy conduction of sound waves through the skin. You will not hear or feel any waves. The gel itself is hypoallergenic and non-sensitizing and will not stain clothes.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study briefly between your evaluations on the field until the evaluation gets done in the ED. If you are admitted for inpatient evaluation, you will stay in the study until the time of your discharge.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves no more than minimal risk to you. Risks and side effects related to using the ultrasound on your skin includes reaction from the gel used for the ultrasound probe. The gel is a neutral hypoallergenic non-sensitizing substance and reaction to the gel is a very rare occurrence. Potentially, the probes could cause a risk of skin irritation. However, this will be monitored by the EMS

performing the scan. The scan takes only a few minutes to perform and will be performed by EMS only when they can safely determine that scanning time will not cause delays in triage, transfer or your care. There have been no cranial ultrasound -related adverse events reported in the literature.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive benefit from participating in the study. However, information gained from this study may benefit other patients by testing the utility of using cranial ultrasound in diagnosis of acute hemorrhagic stroke. Early detection of stroke using ultrasound may help design future studies that could change outcomes.

What Other Choices Are There?

You do not have to be in the study to receive treatment. Your participation is completely voluntary. You will receive standard of care treatment even if you do not take part in the study.

WHAT ARE THE COSTS?

There are no additional costs for being in the study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a research study. This part of the medical record will only be available to people who have authorized access to your medical record. If you have not been a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Clinical Translational Science Institute at Atrium Wake Forest School of Medicine.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

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Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Clinically relevant research results will not be disclosed to you. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with other without additional consent.

What about My Health Information?

In this research study, any data we collect from your procedure is considered Protected Health Information. The information we will collect for this research study includes: age, gender, details of the clinical evaluation done by the EMS and ED and whether they considered you as possibly having an acute stroke, vital signs, and physical exam findings and results of any clinical or diagnostic tests done by the medical team (EMD or ED) taking care of you, among other things.

If this study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries. Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

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Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws. If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. The authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished. You can tell Dr. Aarti Sarwal that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Aarti Sarwal
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Aarti Sarwal at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

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SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature: _____ Date: _____Time: _____ am/pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent: _____Date: _____ Time: _____am/ pm

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject: _____

Legal Representative Signature: _____ Date: _____ Time: _____ am/ pm

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