Informed Consent

Evaluation of a Carbon Nanotube Enabled Solid-State Head CT

NCT number NCT04495634
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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: January 25, 2023
IRB Study # 20-0614
Title of Study: Evaluation of a Carbon Nanotube Enabled Solid-State Head CT
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CONCISE SUMMARY

The purpose of this research study is to compare a new research head scan, called stationary head computed tomography (s-HCT), to the conventional computed tomography (CT) head scan that you will receive as a part of your clinical care. The s-HCT device takes multiple pictures to obtain additional 3-D information about your head, similar to a head CT, but with a different technology to take the images.

You are being asked to take part in this research study because you have either had head trauma or a brain bleed and have undergone a head CT scan in the past 5 days or will undergo a CT scan of your head.

If you decide to take part in this research study, you will undergo one (1) research head CT scan, and we will collect information related to your condition from you and your medical records.

Risks associated with participating in this study include claustrophobia, discomfort from lying on the CT table, and exposure to radiation from the research scan.

With any study, there is a small risk of breach of confidentiality.

There are no direct benefits to you from participating in this study.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to compare a new research head CT scan (s-HCT) to the conventional CT scan that you will receive as a part of your clinical care. The s-HCT device takes multiple pictures to obtain additional 3-D information about your head, similar to a head CT, but with a different technology to take the images. This device is investigational and has not been approved by the FDA.

The proposed research, if successful, will result in a portable method for performing head CTs that can be used for head trauma. The radiation dose of the s-HCT is expected to be no more than the radiation dose of a clinical head CT scan.

You are being asked to be in the study because you have either had head trauma or a brain bleed and have undergone in the past 5 days or will undergo a CT scan of the head.

Are there any reasons you should not be in this study?
You should not be in this study if you are less than 18 years of age, unable to give consent, or have severe claustrophobia.

How many people will take part in this study?
Approximately 50 people at this institution will take part in this study.

How long will your part in this study last?
Your participation will be limited to a single visit, which will include the s-HCT scan. The study scan visit will take approximately 1 hour to complete. We will also follow your medical records for 3 months after the research imaging.

What will happen if you take part in the study?

Once you sign the consent forms, either the research coordinator or the radiology technologist will then escort you to the study room for the imaging exam. You should not wear any head jewelry during the scan.

You will have the s-HCT scan performed in a similar manner as the head CT. You will lie on the patient table, and the technologist will position your head in the s-HCT system. Once positioned, the total scan time is a few minutes. The length of time for the positioning and examination of your head may vary, but it is expected that the entire imaging procedure will take about 5-10 minutes, including the positioning time.

The visit may last up to an hour, including the time to review and sign the informed consent document. Since this is an experimental device, you would not receive any results from the scan and it would not be used to help guide your care in any way.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

CT scan

Computed Tomography or CT scan is a non-invasive procedure that uses special x-ray equipment to take pictures of internal organs, bones and other tissue inside the body. A CT scanning machine is a large machine that is shaped rather like a doughnut with a kind of table that you lie on. The table can slide backwards and forwards through the hole of the doughnut. The pictures are taken as you move through the machine. Claustrophobia (fear of being enclosed in tight spaces) may occur during the procedure and the noise of the x-ray machine could be uncomfortable. Some people may feel discomfort lying on the CT table or may experience anxiety while the table slides in and out of the CT scanner.

This research study involves exposure to radiation from the s-HCT scan. The average person in the United States receives a radiation exposure of 0.3 rem (or 300 mrem) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil.

The estimated additional radiation dose is 25 mrem. The additional radiation dose that you will receive in this study is equal to the radiation everyone receives in 30 days from natural sources. This radiation exposure involves a small risk and is necessary to obtain the information desired. The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care.

Scans that use radiation that do not expose the abdomen (stomach) and reproductive organs directly, similar to this study's imaging, are considered to be safe for an unborn child (https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/x-rays-pregnancy-and-you). However, as this type of scan is being studied and is investigational, there may be risks that are unknown.

If you choose not to be in the study, what other treatment options do you have?
You do not have to be in this research study in order to receive your previously planned treatment.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

The imaging we are using in this research study is not the same quality as imaging that you may have as part of your health care. The images will not be reviewed by a doctor who normally reads such images (such as a radiologist). As a result, you may not be informed of any unexpected findings. The results will not be placed in your medical record. Occasionally the technologist or principal investigator may notice something abnormal on the imaging. If this does occur, the images will be reviewed by a qualified doctor to determine if there is anything of clinical importance. If something is found to be important then you, and/or your primary care provider will be notified. Any further follow up and costs associated with the incidental finding will be your responsibility. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

Do you wish to be informed in case of clinical/relevant unexpected findings? Please initial in the box below if you do not wish to be notified of clinical/relevant unexpected findings. If you do not initial in the box, you will be notified of any findings.

_____ I do not wish to be notified.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the

United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will be receiving $50 and a parking voucher for taking part in this study. Any payment

provided for participation in this study may be subject to applicable tax withholding obligations

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the Department of Defense (DOD) (the sponsor). This means that the research team is being paid by the sponsor for doing the study. XinTek/XinRay Systems/NuRay is a company involved in this research because it owns or makes a device that is being used in this study. Drs. Yueh Lee and Christy Inscoe, co-investigators on this study, are co-inventors of the imaging technology which will be used to conduct this research. UNC-Chapel Hill also owns the initial patent for the licensed technology (device and imaging technology) and a small portion of the company. If this technology or approach is successful at some point in the future, Dr. Lee, Christy Inscoe, and UNC-Chapel Hill may receive financial benefits.

If you would like more information, please ask the researchers listed in the first page of this form.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on 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 at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent