STUDY INFORMED CONSENT

Wrist Fracture Evaluation with a Desktop Orthopedic Tomosynthesis System

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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 26, 2021
IRB Study # 18-3132
Title of Study: Wrist Fracture Evaluation with a Desktop Orthopedic Tomosynthesis System
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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 evaluate an investigational x-ray device that we call "Tomo-E" to provide 3D x-ray pictures of your wrist. We are testing this machine to compare the images to standard x-rays.

You are being asked to be in the study because you are scheduled for or recently had x-ray imaging of wrist for a potential fracture or break of the wrist or surrounding bones.

Are there any reasons you should not be in this study?
You should not be in this study if you will have any surgical procedure after your x-ray and before the research scan.

How many people will take part in this study?
There will be approximately 50 people in this research study.

How long will your part in this study last?
Your participation in the study will last about 1 hour. The length of time for the positioning and examination of your wrist may vary, but it is expected that the entire imaging procedure will take about 5-10 min, including positioning time. We will follow your medical record for 2 months after the research scan.

What will happen if you take part in the study?
If you agree to participate, you will be scheduled for receive a research Tomo-E scan, which will be done in a similar way as your x-ray scan. We will then follow your medical record for 2 months to confirm whether your wrist or surrounding bones was broken.

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.

Risks associated with radiation exposure:
This research study involves exposure to radiation from a research 3D x-ray scan (Tomo-E). Please note that this radiation exposure is not necessary for your medical care and is for research purposes only.

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 dose that you will receive from participation in this research study is less than amount you receive from these natural sources in one year.

The amount of radiation you will receive in this study has a minimal risk and is below the dose guideline established by The University of North Carolina Radiation Safety Committee for research subjects.

Since this imaging involves the wrist, there are no known risks to a fetus if you are or become pregnant. However, the particular x-ray scan may involve risks to the subject (or to the embryo or fetus, if you are or become pregnant), which are currently unforeseeable. You may find more information about this at https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/x-rays-pregnancy-and-you.

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 Tomo-E scan we are using in this research study is not the same quality as an x-ray scan that you may have as part of your health care. The images from the Tomo-E scan will not be reviewed by a doctor who normally reads such images (such as a radiologist) until the research scans have been completed for all subjects. As a result, you may not be informed of any unexpected findings. The results of your Tomo-E scan 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 radiologist 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 on the line below if you do not wish to be notified of clinical/relevant unexpected findings. If you do not initial below, 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. 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.

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care,

but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

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.

Will you receive anything for being in this study?
You will be receiving $25 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 supported by UNC-Chapel Hill (the sponsor). In addition, Drs. Yueh Lee and Christy Inscoe, co-investigators on this study, have an inventorship interest in a device used in this study and owned by XinTek/XinRay Systems. UNC-Chapel Hill has licensed the technology for the device to XinTek/XinRay and also has a small portion of ownership in the company. If this technology or approach is successful at some point in the future, Dr. Lee, Dr. 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

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Printed Name of Research Team Member Obtaining Consent