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Title of Study: **Pilot Study of Dual-Energy Computed Tomography in Stage III Non-Small Cell Lung Cancer**

Sponsor: **Departmental Funding**

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients."

Why are you being invited to participate in this study?

You are being asked to take part in this study because you have been diagnosed with Stage III non-small cell lung cancer (NSCLC) and your treatment plan consists of either chemoradiotherapy or preoperative chemoradiotherapy followed by surgery.

What is the purpose of this study?

The purpose of this study is to evaluate the effectiveness of dual-energy CT (DECT) in the evaluation of tumor response during treatment based on tumor responsiveness.

The study also aims to compare the imaging results using PET-CT and DECT before and 3 months after chemoradiotherapy and the relationship between DECT and the response in subjects undergoing preoperative chemoradiotherapy.

Currently, PET-CT and CT scans are performed to estimate response after chemoradiotherapy.

How many study subjects are expected to take part in the study?

This study will be performed at Rush University Medical Center only and we expect to include a total of 20 subjects; 10 who will undergo chemoradiotherapy only and 10 who will undergo chemoradiotherapy followed by surgery.

What will you be asked to do?

If you decide to participate in this study, you will be asked to complete a questionnaire about your basic demographic information (age, gender, ethnicity), also your medical history, treatment history, history of allergies, kidney function and the ability to tolerate CT contrast agents (dye). This form may be mailed to your home, and you will bring it with you at the time of your first DECT scan.

Subjects receiving preoperative chemoradiotherapy will have DECT scans in addition to standard CT scans at:

- Screening.
- During week 5 of chemoradiotherapy.
- Within one week of planned surgery.

Subjects receiving chemoradiotherapy only will have DECT scans in addition to standard CT scans at:

- Screening.
- During week 5 of chemoradiotherapy.
- 4 weeks after completion of chemoradiotherapy.
- 11-12 weeks after completion of chemoradiotherapy.

All your scheduled DECT scans will be performed at Rush University Medical Center. The DECT scan is not experimental and is performed routinely for many different medical reasons. Routine chest CTs are performed on all lung cancer patients during the course of their treatment although the timing may vary. DECT scan are not routinely used to evaluate patients for lung cancer, however, so its use for this purpose in this study should be considered experimental.

The DECT scan will be performed in the Radiology Department of Rush University Medical Center and will take less than 30 minutes to complete. You will be asked to remove your upper body garments and wear a gown that will be left on during the procedure. An IV (infusion into a vein) will be started and a standard dose IV injection of iodinated CT contrast agent will be given. You will not be required to take any medications by mouth or apply any to your body. At the end of the examination the IV will be removed.

If you are on Metformin (Glucophage) therapy for diabetes, you will be asked to stop the medication for 48 hours after the contrast agent injection.

If you do not have the results of a kidney blood test (serum creatinine) in the last 30 days, one will be performed before the DECT scan. This consists of using about one drop of blood for testing. The blood is drawn from the IV that is inserted for the contrast agent injection. It usually does not involve a separate needle stick.

The results of your scan will be available to your referring physician, in a few hours via the Electronic Medical Records (EMR).

How long will you be in the study?

You will be part of the study for about 12 weeks after initiation of treatment or until you get your surgery.

You may be removed from this study without your consent. Some possible reasons may include the study doctor decides that continued participation in the study will be harmful to you, your disease becomes worse, or the study is canceled.

What are the possible risks of the study?

If you participate in this study, you will undergo three or four DECT scans with IV contrast agents. DECT scans involve radiation and radiation also has the potential to cause cancer, however the dose of radiation that you receive is going to be approximately equal to a regular Chest CT scan and is significantly less than the radiation therapy dose that you would be receiving as part of your treatment.

Although CT iodinated contrast agents are safe and widely used, adverse events can occur. There may be risk of allergy to the contrast agent used in this study. Signs of an allergic reaction may include redness, itching, swelling or (in rare cases) difficulty with breathing, and lightheadedness. Severe allergic reactions may result in death. The majority of side effects are mild, non-life-threatening; events that usually require only observation and supportive measures Severe, sometimes life-threatening, side effects continue to occur unpredictably. Nearly all life-threatening contrast agent reactions occur immediately or within the first 20 minutes after contrast agent injection, during which period you will be observed in the medical center.

Inadvertent contrast agent extravasations [accidental administration of fluids into the space/tissue around infusion sites, either by leakage (because of brittle veins), previous venipuncture (such as from blood drawn for laboratory tests), or direct leakage from mispositioned venous access devices] can occur sometimes. Although most subjects complain of initial swelling or tightness, and/or stinging or burning pain at the site of extravasation, some experience little or no discomfort. Extravasation of an iodinated contrast agent can produce skin breakdown, locally that sometimes peaks in 24 to 48 hours. Usually there is no permanent injury.

A large volume of extravasated contrast agent, defined as 70 cc (14 teaspoons) or greater, can cause local mechanical compression and are evaluated by plastic surgeons to best define therapy.

Are there any anticipated pregnancy risks?

If you are pregnant or breastfeeding, you cannot take part in this study. A pregnancy test **is** required and will be given prior to inclusion in the study. You are responsible for using an effective birth control method such as birth control pills, barrier method (such as condoms or diaphragms), intrauterine device (IUD), hormone implants or surgical sterility while you are taking part in this study. Once you have completed treatment, you may discontinue birth control. If you become pregnant; you must notify the study doctor immediately.

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study**.** This research however will help us evaluate if using DECT scans are beneficial for monitoring the response of stage III lung cancer to therapy. It may indirectly help us answer questions as to which patient would benefit from surgery and which patient would not. This in turn could also help in future lung cancer therapy development.

What other options are there?

Instead of participating in this study, you may choose to continue getting regular chest CT scans as and when prescribed by your doctor.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. Your study questionnaire and other study information will be kept in your study folder, which will be kept in a locked file cabinet in one of the investigator's or study coordinator's offices. Information that will be needed for statistical analysis will be entered into a database, which will also contain data that can be linked to you. This file will be password protected and maintained on a computer in the locked office of one of the investigators or study coordinator.

If you withdraw from this study, the data already collected may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

The results of your DECT scans and any additional test results may be sent to your primary care doctor. The results of these tests will become a part of your electronic medical record at Rush University Medical Center.

Your identity will not be revealed on any report, publication, or at scientific meetings. In order to conduct the study, the study doctors, **(**Jessica Zhou, Palmi Shah) will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, and imaging results and datasets. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

A description of this study will be available on http://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 anytime.

What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as PET-CT scans, CT scans, MRIs, urine pregnancy tests and blood tests that are part of routine care, will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study.

The costs of the DECT scans required for this study and any other tests or procedures performed for only the purposes of the study will be paid by Siemens.

What financial disclosure(s) apply to this study?

Rush University Medical Center is being paid by Siemens Healthcare to conduct this research. A portion of this money may go to your study doctor to compensate for other institutional research related costs.

Will you be compensated or paid?

You will receive $25 per DECT scan performed for this study. You will receive a check in the mail 6 to 8 weeks after each DECT scan directly from the accounting department of Rush University Medical Center.

You may be required to provide your Social Security Number to be paid. If your payment for study participation exceeds $600 per year, this information must be reported to the Internal Revenue Service (IRS).

Your participation in this research study may contribute to the development of commercial products from which others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you or tell you where you can get treatment.

Neither Rush University Medical Center nor Siemens have a program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Jessica Zhou, MD at 312-942-5751. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily.

Signature of Witness/Translator	Date of Signature

☐ Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.