CONSENT FORM TO BE PART OF A RESEARCH STUDY

TITLE OF RESEARCH: **Feasibility and Accuracy of hybrid Magnetic resonance and Positron Emission Tomography with 18F-Fluorodeoxyglucose in diagnosing cardiac sarcoidosis.**

IRB PROTOCOL: **IRB-300002877**

INVESTIGATOR: **Navkaranbir S Bajaj MD, MPH**

SPONSOR: **UAB School of Medicine and the Department of Radiology**
CCTS Pilot Research Initiative

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to assess the capabilities of UAB's FDG-PET/CMRI scanner in diagnosing cardiac sarcoidosis.
Duration & Visits	The study will involve a single visit that will take approximately 2 hours.
Overview of Procedures	You are scheduled for an FDG-PET/CT scan as part of your normal clinical care. For the study, the FDG-PET/CT scan will immediately be followed by a different scan called FDG-PET/CMRI. As part of this additional scan, you will receive I.V. contrast and then we will obtain additional pictures of your heart in the MRI scanner. We will also collect information about you from your medical record.
Risks	The most common risk is the risk of radiation from the scan. The radiation is approximately equal to 3 years of exposure to natural background radiation. Background radiation is radiation normally received from sources such as cosmic rays and natural radioactivity in building materials and the ground. There is a small risk that the radiation may cause cancer or other radiation effects in several years. As the study also involves an MRI, the most common risks are the following: • Discomfort from laying in the scanner • Claustrophobia • Muscle twitching • Loud noises (ear plugs will be provided to reduce noise)
Benefits	You will not benefit from taking part in the study.
Alternatives	The alternative is to not participate in the study.

Purpose of the Research Study

Sarcoidosis is a disease that affects various parts of the body including the heart. Those with heart involvement are at increased risk of dying. Currently, two commonly utilized tests to diagnose cardiac sarcoidosis (CS) are 18F-fluorodeoxyglucose (18F-FDG) Positron Emission Tomography (18F-FDG-PET) and Cardiac Magnetic Resonance Imaging (CMRI). While FDG-PET/CT good at detecting early CS, CMRI can identify the disease at later stages; however, depending upon the test selected and the stage of the disease, the diagnosis of CS can be missed. The simultaneous FDG-PET/CMRI scanner combines both the CMRI and the FDG-PET/CT imaging into one machine, thereby, increasing the chances of diagnosing CS. However, this technology is new, and only a handful of centers across the world have access to it. The purpose of this study is to establish the ability of the FDG-PET/CMRI machine to diagnose CS. Our study will include 15 patients at UAB who are suspected to have CS.

Study Participation & Procedures

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

This study will take place at the Advanced Imaging Facility in the basement of the UAB Cancer Center. This is located at 500 26nd Street South, Birmingham, Alabama 35233.

The standard of care in the diagnosis of CS is either an FDG-PET/CT or CMRI imaging test. While FDG-PET/CT is good at diagnosing CS at an early stage, the CMRI is better at diagnosing CS at a later stage. Therefore, depending upon the stage of the disease and of the two imaging test selected, the diagnosis of CS can sometimes be missed. However, we now have an imaging machine which combines both the FDG-PET/CT and CMRI into one device, FDG-PET/CMRI; combining the benefits of both with significantly lesser radiation to the patient in comparison to the FDG-PET/CT due to the replacement of the CT with the CMRI.

If you decide to participate in the study and qualify for it, we will take your permission to participate in the form of your signed informed consent form after we explain about the benefits and potential risks of FDG-PET/CMRI, and answer all your questions to your satisfaction. The consent will be taken at the time of your clinic visit with your sarcoidosis specialist doctor. Your doctor will order the FGD-PET/CT scan as the standard of care for the diagnosis of CS which will not be a part of our research. If you are a female of child-bearing age, you will asked to provide a urine sample prior to the scan to be tested for pregnancy.
On the day of your test, you will first undergo the FDG-PET/CT scan followed by FDG-PET/CMRI scan. The FDG-PET/CT scan ordered by your physician involves lying still on your back inside the scanner for approximately 30 minutes. The FDG-PET/CMRI, which will be done solely for the research purpose will be 60 – 90 minutes long will be done within an hour of the FDG-PET/CT scan. As a part of CMRI study for the diagnosis of CS, Gadolinium contrast will be given by injection into a vein which will help in distinguishing normal from abnormal tissues found in CS. Gadolinium contrast you will receive has been determined to be safe and effective by the U.S.

Food and Drug Administration (FDA) and has been used in about 1 in 3 of CMRI scans nationwide over the last 30 years. Electrocardiogram (ECG) electrodes will be placed on your skin to measure the heart rate for the CMRI scan. You will be in communication with a CMRI technician through an intercom at all times.

In this study, you will be exposed to some radiation from the FDG-PET scan. The radiation from this extra scan is approximately equal to 3 years of exposure to natural background radiation; if you do not participate in this study, you will receive a FDG-PET/CT scan approximately equal to 5 years of background radiation. Background radiation is radiation normally received from sources such as cosmic rays and natural radioactivity in building materials and the ground. There is a small risk that the radiation may cause cancer or other radiation effects in several years.

Besides recording the images findings, we also record your health information obtained from the electronic medical record (EMR) into our data collection form of the study which will be used to analyze the findings to arrive at the results of the study.

We are performing imaging solely for the research purposes described above. It is not a clinical scan intended for diagnostic or therapeutic purposes. Under no circumstance will the investigator, research staff, or imaging staff interpret the scan as normal or abnormal. They are unable to make any medical comments about your scan. The scan will not be looked at or read for any healthcare treatment or diagnostic purpose. If you want your scan to be reviewed by a physician so the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge. Below are incidental findings that may be observed in the scan:

- Simple renal cyst
- Hepatic cyst
- Pleural effusion
- Mediastinal lymphadenopathy/mass
- Liver haemangioma

The clinical results (including individual research results) will not be returned to you.

Risks and Discomforts

The following are potential risks from participating in the study:

Peripheral intravenous (I.V.) catheter placement:

There is a small chance of bleeding, bruising, and/or pain at the site of I.V.catheter placement. Some people become dizzy or feel faint. There is a rare risk of infection. To minimize these risks, experienced medical personnel will place the I.V. using aseptic (clean) technique.

Positron emission tomography (PET) scan:

This dose from the imaging agent used in the scan (FDG) is equal to approximately 2.3 years of natural background radiation in the United States. This amount of radiation may cause a small increase in risk of cancer years after this study.

Magnetic resonance imaging (MRI):

The most common reversible side effects of the imaging agent used in the scan (gadolinium) are headache, nausea, injection site coldness/localized coldness and dizziness. These are present in ≥1% of patients.

There is <1% chance of an irreversible side effect known as Nephrogenic Systemic Fibrosis(NSF) with the highest risk amongst patient with chronic, severe renal disease. If you have severe renal disease you will be ineligible for the study.

MRI uses a strong magnetic field and non-ionizing radiofrequency pulses to generate images of the human body. These images can provide functional information about the heart. Some people cannot have an MRI because they have some type of metal in their body. Types of devices and metal that may preclude MRI include some cardiac pacemakers, artificial heart valves, metal implants such as metal ear implants, bullet pieces, chemotherapy or insulin pumps or any other metal such as metal clips or rings. If you have any of these devices you will be excluded from the study. During this test, you will lie in a small closed area inside a large magnetic tube. Some people are scared or anxious in small places (claustrophobic). The MRI scanner makes loud banging noises while taking a measurement, so either ear plugs or specially designed headphones will be used to reduce the noise. Outside of these precautions, the MRI techniques used here have an established safety profile and are considered low-risk across multiple exposures and will not increase your risk of injury or disease.

Each risk listed above has a low frequency of occurrence and in most cases severity is low and completely reversible. The frequency of cancer arising from radiation related to FDG is very low but the severity and reversibility are variable depending on the type of cancer.

You will not be able to participate in the FDG-PET/CMRI study if you have the following

- Implanted metallic devices in your body
- Permanent pacemakers
- Neurostimulators
- Defibrillators
- Cochlear implants
- A significant fear of enclosed spaces also known as claustrophobia
- Previous allergic reaction to gadolinium and severe kidney disease

- If you are pregnant or think you might be pregnant

Loss of confidentiality:
There is also some risk associated with the potential breach of confidentiality.

There is a risk that someone in the future could link your genetic or medical information stored in the databases back to you. If your information suggested something serious about your health, it could be misused. It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. We believe the chance these things will happen is very small, but we cannot guarantee that your identity will never become known. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them.

Information for Women of Childbearing Potential and Nursing Mothers

If you are pregnant, you should not participate in this study. Women who can become pregnant must take a pregnancy test before the start of the study.

Benefits

You may not personally benefit from your participation in this research; however, your participation may provide valuable information to the medical community about the validity of the hybrid combined FDG-PET/CT and CMRI scans. If validated, the information gained by this study may significantly contribute to cardiovascular healthcare by allowing to perform two different imaging modalities by one test, which will improve the diagnostic accuracy, reduce cost and also limit radiation by eliminating the need for CT scan as used for conventional FDG-PET/CT studies.

Alternatives

Your alternative is to not participate in this study. There will be no penalty to you if you choose not to participate in the study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Your consent form will be placed in your medical record at UAB Health System This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient), a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

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.

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the

sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care. Contact the study doctor if you want to withdraw from the study.

You may be removed from the study without your consent if the study doctor decides it is not in the best interest of your health.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

Because you are undergoing a FDG-PET/CT scan that was requested by your doctor for a clinical purpose, the usual charges for the standard FDG-PET/CT examination will apply and costs will be billed to you and/or your insurance company in the usual manner. Enrollment in this study involves an additional scan, which will be solely done for research purpose, and you will not incur any extra cost. The costs of any other standard medical care, which is not related to research CMRI scan, will be billed to you and/or your insurance company in the usual manner.

Payment for Participation

There is no compensation for participation

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Bajaj at (205) 975-7123 or after hours by paging him at (205) 934-3411.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date