

Procedures/risks: Radiology (CT, DXA, MRI, ultrasound, X-ray)

Computerized Axial Tomography (CT):

Procedure: A Computerized Axial Tomography (CT) scan [of your heart] involves holding your breath for a brief period of time (usually a few seconds) after a small dose of contrast/dye is injected into an intravenous line. You will have an intravenous catheter placed in your arm to administer the contrast agent. You will lie on a flat table that slides into a short, round CT scanner that detects the presence of dye in the heart and the arteries supplying the heart. A computer connected to the scanner makes images of the heart and arteries.

The CT Scan [of the abdomen] is a standard procedure to measure structures inside the body/ of the body [e.g., total body fat of the abdomen]. You will lie flat on your back on the CT Scan table with your shoes off and minimal clothing. The machine will take one picture of your body [abdominal area]. At the completion of the test, the computer of the machine will generate images or pictures of your body [the fat content in your abdomen]. The x-ray emitted as part of the CT Scanning is 6 times that of a chest x-ray.

Risks: Lying on a flat table for a few minutes may be uncomfortable. Occasionally, during a CT scan, some patients have experienced a feeling of being 'closed in' or rarely, claustrophobia. The radiation exposure of an abdominal CT scan is about 6 times the amount of exposure of a chest x-ray. [For the purposes of this study, there will only be one (1) slice or picture of the abdomen taken, rather than a full abdominal CT Scan.]

In order to see the blood vessels better during the CT scan, contrast agent must be injected. Any time a contrast agent is injected, there is the rare possibility of affecting the kidney. This is more likely if kidney function is already abnormal. If your kidney function is abnormal, then you will not be enrolled in this research study. There is also a chance that you may experience an allergic reaction to the contrast agent that will be used for the CT. Such a reaction is unlikely to occur especially if you have never had a reaction to this type of contrast agent in the past. There is about a 1 in 40,000 risk that anaphylactic shock (a serious and possibly life threatening allergic reaction) may result from the use of the CT contrast agent. The injection of the contrast agent may result in some discomfort as well as the possibilities of a general feeling of warmth, coolness or a sensation of local pressure or pain at the injection site. Less frequently reported side effects include dizziness, nausea, headache and a metallic taste in the mouth. Rare reactions include vomiting, drowsiness, visual disturbances, difficulty breathing, chest pain, increased heart rate, or allergy-like symptoms such as hives, itching or an irritation in the throat. Severe allergy-like reactions, if not treated, may result in death. However, for this study all CT scans will be performed where the necessary emergency medical equipment is immediately available should the need arise. In addition, you will be in continuous contact with a technologist and a physician and/or nurse who is readily available.

If you have a contrast allergy or any other factors that would prohibit you from safely and effectively participating in this study, please give this information to any member of the research team before you decide to participate in the study. For your safety you would not be eligible to participate in this study.

When the contrast dye is injected during the CT scan, you may have a feeling of warmth spread throughout my body. You may have a salty taste in my mouth.

You could have an allergic reaction to the dye and may feel nauseated (like the need to throw up), vomit (throw up), sneeze, get hives on your skin, or have itchy skin. The most common contrast dye contains iodine. If you know that you are allergic to contrast dye or iodine, you are to tell the study doctor. A rare but very serious allergic reaction to contrast dye is known as anaphylaxis (a life threatening swelling of the airway). If you begin to feel short of breath after the contrast dye is injected into your vein, then you should immediately tell the person taking the scan. If this rare reaction does take place, the procedure will be stopped, and you will be monitored by a physician.

You must not move during the test; just relax and breathe normally. You might be uncomfortable while you are in the tunnel-shaped machine. Some people have felt claustrophobic during the test (feeling of being closed in because the space feels too small). If you become uncomfortable and feel like you are closed in, you are to tell the person taking the scan right away so that person can help you. If you know that you are claustrophobic, then tell your study doctor. There may be medication that can help you feel more relaxed during the procedure.

The total body CT scan exposes you to a limited amount of radiation. The amount is similar to that from 100 chest x-rays and is similar to that received during a diagnostic cardiac catheterization procedure. It is also about one-third the amount received during a nuclear medicine stress test.

It is unsafe for a pregnant women to undergo a CT scan. Therefore pregnant women will not be recruited nor be eligible to participate in this study. For all women of childbearing potential, a urine or serum pregnancy test will be performed [at the beginning of the study]. The cost of the pregnancy test, if indicated, will be performed at no cost to you. Results of the pregnancy test will be given to you.

Contrast Dye (iohexol)

Procedure: A small (1 teaspoon) dose of intravenous (IV) “dye” (iohexol, which is used for many radiological procedures, e.g. x-rays, CT scans, etc.) will be given intravenously in order to better measure your body’s functions [name specific function(s)].

Risks: You will be given some “dye”. Some people develop allergic reactions to this dye. If you have a history of this, or a history of an allergic reaction to iodine or seafood, you will not be given the dye. However, there is a small chance that you may have a reaction to the dye. Such a reaction may be minor, for example itching and/or skin rash. Rarely, an allergic reaction can be severe, requiring emergency treatment with medications, hospitalization, or even death. X-ray dye can cause temporary kidney damage, but the amount of X-ray dye used in this study is at least only one-fifth of the amount that has been reported to cause this kind of kidney damage.

There is no evidence that the small amount of x-ray dye used for this testing is damaging to the kidney.

Due to the unknown risks and potential harm to the unborn fetus, women who may become pregnant should not receive the dye. If you are a woman of childbearing potential you will undergo a pregnancy test prior to receiving the dye for the test at time that this procedure is scheduled during this research study.

D[E]XA

Procedure: Dual-energy x-ray absorptiometry (DXA or DEXA) is a standard procedure to measure body composition. It measures whole body fat, lean body mass (muscle) and bone density as well as regional body fat. After a technician has explained the procedure to you, you will lie flat on the DEXA table. X-rays from the machine will be introduced into your body. The absorption of the x-rays of your body tissue will be determined by the computer in the machine.

Your muscle mass will be measured using a low dose x-ray machine (dual energy x-ray absorptiometry or D[E]XA). We will ask you to lie still for about 5-10 minutes while the D[E]XA machine scans over your body. This procedure is not painful, but there could be some minor discomfort from lying in the same position.

Risk: The radiation emitted from the D[E]XA is less than that of a chest x-ray.

The radiation exposure from the bone density machine (DEXA) is usually compared to the amount of exposure from one chest x-ray. Therefore, risks associated with DEXA are similar to exposure from a chest x-ray. Similarly, the bioelectrical impedance analyzer (BIA) is associated with minimal electrical current similar to that of electrocardiogram (EKG), a machine that is routinely used to measure heart beat and heart rhythm.

During the DEXA scanning, you will be exposed to a tiny amount of radioactivity. The amount of radioactivity is equivalent to the amount you are exposed to when you are outside for five hours. There may be some minor discomfort from lying in the same position for 5 to 10 minutes while having the DEXA scan.

The amount of radiation you will be exposed to from the DEXA scan is extremely small. This is a standard test that is performed in the study exactly the same as it is for regular patient care. The exposures for the DEXA are as follows: about 0.04 mrem (mrem is the standard unit of radiation exposure) from the whole body; 3.7 mrem (average adult) each from the hip and spine and 0.2 mrem from the forearm. In comparison, a typical airplane flight from Columbus to Los Angeles would expose your whole body to about 30 mrem of radiation and the annual natural exposure of radiation in Columbus is about 300 mrem per year. Any dose of radiation could be potentially harmful, but the risks that you will be exposed to are so small that they are difficult to measure. If you have had more than 5-10 x-ray procedures in the last year, you should discuss this with the investigator.

DEXA scans expose your body to radiation. Although it can vary from person to person, your whole-body radiation exposure is equivalent to approximately 3% of the amount of exposure a person in the U.S. receives from natural background radiation. The risk of harm from this amount of radiation is low and no harmful health effects are expected; however, your risk of harmful effects may increase if you are exposed to more procedures that involve radiation.

You may experience a small amount of discomfort while being placed on the examination table or while lying down for the D[E]XA. This discomfort will be minimized by keeping the time involved in making the measurements as short as possible, and by allowing you a break if necessary.

Magnetic Resonance Imaging (MRI):

Procedure: You will undergo a magnetic resonance imaging (MRI) scan. Instead of using radiation (x-rays), MRI uses a powerful magnetic field (1.5 Tesla) and radio frequency waves. Many changes in body tissues can be evaluated by MRI. [The body is made up of atoms. These atoms have a magnetic charge. When the body is placed in a magnetic field, these atoms tend to line up with the magnetic field. Radio waves (similar to those used for TV) are then sent into the body, which alters the alignment of the atoms. When the radio waves are stopped, the atoms generate a weak radio signal that the machine detects. These radio signals are then processed by a computer. The result is an image that looks like the structures of the human body.] For the specifics of this study, the image will look like XXXX. [Since different tissues (heart muscle, arteries, etc.) have different magnetic properties, they will appear different on MRI images resulting in pictures of these structures.] You will be asked to remove all metal objects from your person. You may be asked to remove clothing and put on a hospital gown. You will lie on a flat table that slides into a round, full body clinical MRI scanner.

Risks: Risks of having a MRI are much the same as the risks for having a CT scan. But in addition to those risks, you are ***not*** allowed to have any metal objects in or on your body because a MRI uses a powerful magnet that could cause a damaging pull on the objects. For example, you cannot have a MRI if you have a pacemaker or a metal pin in your body. You are to tell the study doctor if you have any metal objects in or on your body.

It is possible that you could feel stress and/or claustrophobia (fear of enclosed spaces) during the MRI scans. Excessive levels of stress can pose risks to your health. The scans may take a long period of time (up to one hour) and it is possible that you may feel some discomfort related to lying on your back for that period of time. You may also experience fatigue during completion of the tasks presented to you. If you feel fatigue you can ask for a break. If you feel claustrophobic you can ask to end the study and you will be taken out of the MRI scanner.

You will be able to speak to investigators and/or technician(s) at any time during the procedures if you have any concerns or difficulties.

As is common for routine clinical MRI exams, you will be asked to wear earplugs in order to reduce noise from the MRI system.

The MRI magnet itself has been classified by the United States Food & Drug Administration (FDA) as a device with non-significant risk, and the MRI systems used in this experiment are all FDA approved for routine clinical use. Exposures to magnetic fields and radio waves will be within the FDA approved limits. **If you have metallic objects in your body, you must inform the research team, since the magnetic field may affect this object in a significant manner that can harm you.**

Possible discomforts associated with being in the MRI scanner include noise from the magnet, which can be minimized with soft earplugs. You may also experience a sense of claustrophobia (a feeling of being closed in or trapped in a small space). Subjects with metallic foreign bodies, a cardiac pacemaker, an electronic stimulator, cerebral aneurysm clips or any metallic implant that is not compatible with the MRI machine, will not be allowed to be enrolled in the study.

Subjects with coronary (around the heart) stents are candidates if they fall within the approved manufacturer MR safety guidelines and recommendations. There is a risk of movement or dislodgment of metal objects if overlooked during the screening process. In addition, an increase in the temperature of the object may occur.

Although there have been no demonstrated effects of MRI in pregnancy, its safety remains unproven. Therefore pregnant females will not be recruited. Females of childbearing potential will be questioned as to whether or not they are pregnant, if there is any doubt a urine/serum pregnancy test will be performed. If a pregnancy test is conducted, then you will be notified of the results.

MRI (cardiac):

Procedure: You will undergo a cardiac magnetic resonance imaging scan (CMR), also known as heart MRI. Instead of using radiation (x rays), MRI uses a powerful magnetic field (1.5 Tesla) and radio frequency waves. Many changes in tissue can be evaluated by MRI. The result is an image that looks like the body's anatomy, for the specifics of this study, the image will look at your heart. [Since different tissues (arteries, muscle, etc.) have different magnetic properties, they will appear different on MRI images resulting in very clear pictures of the heart and heart arteries.] You will be asked to remove all metal objects. You may be asked to remove clothing and put on a hospital gown. An intravenous catheter (IV) will be placed in your arm or hand vein to deliver contrast material and/or medication during the scan. You will lie on a flat table that slides into a round, full body clinical MRI scanner. For this study, a contrast agent (material used to make tissue more visible, sometimes referred to dye) will be used in addition to routine cardiac MRI techniques.

Risk: (see Magnetic Resonance Imaging)

There is very small chance that you may have an allergic reaction to the contrast agent (gadolinium) that will be administered through the IV [for the CMR exam]. Other risks include headache, nausea, local pain, or hypotension (low blood pressure). Only about 3 out of 10,000

people experience any type of reaction to the [CMR] contrast agent. Severe allergy-like reaction, if not treated, may result in death.

The MRI facility is equipped with all the necessary equipment and personnel to handle this situation, if it should it arise. If you have a known contrast allergy or any other factors that would prohibit you from safely and effectively participating in this study, you will not be enrolled. You will be monitored at all times by a nurse, physician and technologist during the administration of medications. The staff have immediate access to the emergency equipment should the need arise.

Ultrasound

Procedure: An ultrasound is a test that uses sound waves to get a picture of your insides, in this case your [anatomical structure]. You will lie on a table and the doctor or nurse will use a transducer (hand-held device) and gel that is applied to your skin, running the transducer over the skin of your abdomen. Ultrasound waves cause no sensation, and the only thing you will feel is the pressure of the transducer on your skin.

Risks: There are no known risks to you [or to the developing fetus] from the use of ultrasound.

X-Ray

Procedure: You will have a chest X-ray to [check the placement of the central venous catheter].

[Additional X-rays may be done at any time if we think there is a problem with the catheter].

The chest X-ray will expose you to 8 millirem (mrem) of radiation. A millirem (mrem) is the the amount of radiation is measured. This amount of radiation is equal to about 3% of the annual radiation one is usually exposed to each year from the earth and the sky.

Risks: When you have a chest x-ray, you will be exposed to low levels of radiation. There is a very slight chance of damage to cells or tissues from radiation.