

Risks and Inconveniences

Magnetic resonance (MR) is a technique that uses magnetism and radio waves, not x-rays, to take pictures and measure chemicals of different parts of the body. The United States Food and Drug Administration (FDA) has set guidelines for magnet strength and exposure to radio waves, and we carefully observe those guidelines.

Subjects will be watched closely throughout the MR study. Some people may feel uncomfortable or anxious. If this happens, a subject may ask to stop the study at any time and we will take them out of the MR scanner. On rare occasions, some people might feel dizzy, get an upset stomach, have a metallic taste or feel tingling sensations or muscle twitches. These sensations usually go away quickly but subjects will be encouraged to tell the research staff if they experience them.

There are some risks with an MR study for certain people. If an individual has a pacemaker or some metal objects inside their body, they may not be able to participate in this study because the strong magnets in the MR scanner might harm them. Another risk is the possibility of metal objects being pulled into the magnet and hitting them. To lower this risk, all people involved with the study must remove all metal from their clothing and all metal objects from their pockets. We also ask all people involved with the study to walk through a detector designed to detect metal objects. It is important that everyone (study staff and participants) know that no metal can be brought into the magnet room at any time. Also, once a subject is in the magnet, the door to the room will be closed so that no one from outside can accidentally go near the magnet.

We will encourage subjects to read and answer very carefully the questions on the MR Safety Questionnaire related to their personal safety.

This MR study is for research purposes only and is not in any way a complete health care imaging examination. The scans performed in this study are not designed to find abnormalities. The principal investigator, the lab, the MR technologist, and the Magnetic Resonance Research Center are not qualified to interpret the MR scans and are not responsible for providing a health care evaluation of the images. If a worrisome finding is seen on a scan, a radiologist or another physician will be asked to review the relevant images. Based on his or her recommendation (if any), the principal investigator or consulting physician will contact the subject, inform them of the finding, and recommend that they seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie only with the subject and their physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that they receive based on these findings. The images collected in this study are not a health care MR exam and for that reason, they will not be routinely made available for health care purposes.

If contrast is used, also include the following:

Contrast Risks and Procedures Statements.

Having an intravenous (IV) line placed is a very safe procedure. There is a slight chance that multiple needle-sticks will be needed to make sure the IV is placed correctly. A subject might feel a small amount of pain when the IV is placed but it does not last very long. A bruise or a minor infection might develop where the IV is placed. A bruise will go away by itself and it might help if the subject wraps a warm towel around their arm. Infections can also be treated if necessary.

The FDA approves the contrast agent Gadolinium for use with human participants. We will inform subjects that there are certain risks associated with the use of that contrast. Some healthy subjects (fewer than 3%) may experience mild nausea, headache or dizziness after the injection. These side effects usually go away without need for treatment. There is also a risk of allergic reaction (less than 1%). An allergic reaction can cause hives and itching or difficulty breathing. In individuals with kidney dysfunction, the gadolinium can cause a serious condition called nephrogenic systemic fibrosis. This is why prior to an MR study subjects may have to undergo blood work to make sure that their kidney function is normal. Detailed information on the contrast agent Gadolinium will be provided to them at their request.

Subjects will be asked if: (1) if they are pregnant or breast feeding, (2) if they have a history of allergic reactions to MR or CT contrast agents, (3) if they have a history of kidney disease, seizure, asthma, or allergic respiratory disorders, and (4) if they have anemia or disease that affects red blood cells.