

## Informed Consent for Risks of Gadolinium Contrast

As part of the MRI examination, your referring physician and the radiologist have deemed it advisable to give you an intravenous injection of gadolinium, a contrast agent used in MRI. This injection increases the accuracy of the scan to better diagnose your condition. Gadolinium contrast agents have been used safely in millions of cases, but minor reactions (headaches, nausea, or itchiness) occur in about 2% of patients and rare life-threatening reactions have been reported.<sup>1</sup> For some patients, Nephrogenic Systemic Fibrosis (NSF)/Nephrogenic Fibrosing Dermopathy (NFD) is a concern. It was first described in medical literature in 2000. This disease is seen in patients that have noticeably advanced renal failure. NSF/NFD causes fibrosis of the skin and connective tissues throughout the body. Patients develop skin thickening that may prevent bending and extending joints, resulting in decreased mobility of joints. In addition, patients may experience fibrosis that has spread to other parts of the body such as the diaphragm, muscles in the thigh and lower abdomen, and the interior areas of the lung vessels. The clinical course of NSF/NFD is progressive and may be fatal. The primary risk factor is reduced renal function. NSF/NFD is a very rare fibrosing condition of the skin and organs that has been reported in patients receiving MRI with gadolinium. It can cause permanent disability and death.<sup>2</sup>

Breast feeding mothers: There is a very small percentage of contrast material that is excreted into the breast milk and absorbed by the infant. Available data suggest it is safe to continue breast feeding. However, if you are concerned, you may abstain from breast feeding for 12 to 24 hours (express and discard breast milk).

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<sup>1</sup>Allergic reaction with less than on in 300,000 chances that this will be severe. A metallic taste in the mouth, tingling in the arm, nausea or headache found in less than 1% of patients.

<sup>2</sup> Alternatives: In some cases, a CT scan with iodine may be an alternative.

SOURCES: <a href="http://www.rad.jhmi.edu/mri/MRI\_dialysis\_gadolinium.htm">http://www.fda.gov/Drugs/DrugSafety/DrugSafety/DrugSafety/Newsletter/ucm142889.htm</a> "Questions and Answers on Gadolinium-Based Contrast Agents"

http://www.fda.gov/Safety/Med/Watch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm152672.htm "Gadolinium-containing Contrast Agents for Magnetic Resonance Imaging (MRI)"

http://radiology.yale.edu/patientcare/gadolinium.html "Guidelines for Administration of Gadolinium Based Contrast Agents (GBCAs) for MRI –(November 2007)"