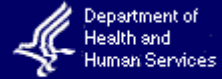


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## Public Health Advisory

### Update on Magnetic Resonance Imaging (MRI) Contrast Agents Containing Gadolinium and Nephrogenic Fibrosing Dermopathy

**This information is not current.**  
**The FDA has issued new information about this safety issue, please see**  
<http://www.fda.gov/cder/drug/infopage/gcca/default.htm>.

The FDA has received additional information about a new disease, known as Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF/NFD), which may occur in patients with moderate to end-stage kidney disease after they have had a Magnetic Resonance Imaging (MRI) or Magnetic Resonance Angiography (MRA) scan with a gadolinium-based contrast agent. An MRI scan provides clear and detailed pictures of internal organs. An MRA test uses a gadolinium-based contrast agent to take detailed pictures of blood vessels. During some MRI scans and all MRA scans, a gadolinium-based contrast agent is injected into a patient's vein so blood vessels can be distinguished from other nearby tissues.

As of December 21, 2006, FDA has received reports of 90 patients with moderate to end-stage kidney disease who developed NSF/NFD after they had an MRI or MRA with a gadolinium-based contrast agent. Their NSF/NFD began from 2 days to 18 months after exposure to the contrast agent. Many, but not all of these patients, received a high dose of the contrast agent; some received only one dose. In light of these reports, FDA is notifying health care providers and patients of the following:

- **Patients with moderate to end-stage kidney disease** who receive an MRI or MRA with a gadolinium-based contrast agent may get NSF/NFD which is debilitating and may cause death.
- **Patients who believe they may have NSF/NFD should contact their doctor.** Patients who develop NSF/NFD have areas of tight, rigid skin and may have scarring of their body organs. The signs of NSF/NFD also include: burning, itching, swelling, hardening and tightening of the skin; red or dark patches on the skin; yellow spots on the whites of the eyes; stiffness in joints with trouble moving or straightening the arms, hands, legs, or feet; pain deep in the hip bones or ribs; and muscle weakness.
- **When a patient with moderate to end-stage kidney disease needs an imaging study,**

**select imaging methods other than MRI or MRA with a gadolinium-based contrast agent** for the study whenever possible. If these patients must receive a gadolinium-based contrast agent, prompt dialysis following the MRI or MRA should be considered.


- **The FDA asks health care professionals and patients to report possible cases of NSF/NFD** to the FDA through the MedWatch program by phone (1-800-FDA-1088) or by the Internet at <http://www.fda.gov/medwatch/index.html>.

Worldwide, about 215 patients with NSF/NFD have been reported. Of these reports, the medical histories of 75 of these patients were reviewed in detail, and all of the patients had received a gadolinium-based contrast agent for an MRI or MRA. Researchers have identified gadolinium in skin biopsies of patients with NSF/NFD.

Why NSF/NFD occurs in patients with moderate to end-stage kidney disease who receive gadolinium-based contrast agent is not yet known. The FDA is working with expert scientists to gather additional information about NSF/NFD.

Currently there are five FDA approved gadolinium-based contrast agents, Magnevist, MultiHance, Omniscan, OptiMARK, and ProHance. These contrast agents are FDA approved for use during an MRI scan, but not for use during an MRA scan. Although NSF/NFD has been reported for only 3 of the 5 gadolinium-based contrast agents, FDA believes that there is a potential for NSF/NFD to occur with the use of any of the approved gadolinium-based contrast agents.

You can find more details about NSF/NFD and gadolinium-based contrast agents in FDA's [Information for Healthcare Professionals](#).

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[↑ Back to Top](#)   [↙ Gadolinium-Containing Contrast Agents](#)

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