MCW MRI Safety Policies and Procedures

Gadolinium Use for Research Subjects

Category: Magnetic Resonance Imaging (MRI) Safety

Procedure #: MR.SOP. 04

Applies to: Investigators, study personnel, Medical College of Wisconsin (MCW) staff

PURPOSE:
The purpose of the Gadolinium Use policy is to prevent any research subject from acquiring Nephrogenic Systemic Fibrosis (NSF) due to administration of Gadolinium-based contrast agents (GBCAs) by following American College of Radiology (ACR) (May 2017) version 10.3 guidelines and the updated FDA Medication Guide (May 2018).

It is also the purpose of the GBCA Use policy is to address the FDA issued warning (September 2017) for GBCAs regarding gadolinium retention in certain organs and tissues.

INVESTGATOR JUSTIFICATION:
It is recommended that investigators explore methods other than the use of GBCAs for obtaining tissue contrast in the research study using MRI. Investigators must provide justification for choosing to use a GBCA for basic science research in which the human research participant realizes no benefit from the risk. Investigators may employ more cautious standards than these. Applications indicating a GBCA will be used in the study will be reviewed by the full committee for approval.

Procedure:

1. Pregnant women should not receive gadolinium contrast agents in research studies.
2. Research participants must have a current Glomerular Filtration Rate (GFR) before receiving a GBCA. The GFR value obtained within 6 weeks of the date of MRI scanning should be greater than 60 ml/min/1.73 m^2.
   Research participants at high risk for low GFR values include those with:
   - Renal disease (including solitary kidney, renal transplant, renal tumor)
   - Age over 55.
   - Diabetes – by self-report, on inquiry.
   - Hypertension – by self-report and / or current measurement.
   - Note: If the participant reports a history of proteinuria or chronic Non-Steroidal Anti-Inflammatory Drug (NSAID) use, GFR values may be obtained at the discretion of the PI and/or medical director.
   - Severe hepatic disease, liver transplant or pending liver transplant. GFR assessment as near as possible to administration of Gadolinium.
3. Only Group II GBCAs (see ACR Groups below) should be administered to research participants.
4. Research participants with a history of allergy to MRI GBCAs should not receive the contrast.
5. No research participant should receive a cumulative dose of a GBCA over a 48 hour period that exceeds the FDA recommended dose range.

FDA Medication Guide:

Research participants should have available for review the FDA Medication Guide for Gadolinium / Gadavist
https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/201277s013lbl.pdf#page=37

Injection Procedure:

1. The date of expiration will be verified prior to use.
2. All MRI GBCAs are used from single use vials.
3. GBCAs loaded into an injector syringe in an MRI suite ready for human participant use must be labeled with contrast type, date of load and time of expiration (within one hour).
4. Saline loaded into a power injector syringe in an MRI suite ready for human participant use must be labeled that it is 0.9% sodium chloride with date and time of expiration.
5. Multi use GBCAs and saline practices are prohibited.

Intravenous (IV) Injection Sites and Needle Selection

1. A peripheral IV using a 22g or larger is to be placed in the antecubital vein.
2. Documentation must include
    - Date of injection
    - Name of MRI technologist, nurse, or physician who injected the contrast
    - Brand of Contrast used
    - Dosage of Contrast used
    - Injection site
    - Any adverse reaction or event

This policy is advisory, and the MCW Research MRI Safety Committee will continue to consider each study on its own merits.

Contrast Agents – Current ACR Groups:

Group I: Agents associated with the greatest number of NSF cases:

- Gadodiamide (Omniscan –GE Healthcare)
- Gadopentetate dimeglumine (Magnevist-Bayer Healthcare Pharmaceuticals)
- Gadoversetamide (OptiMARK-Guerbet)

Group II Agents: Agents associated with few if any, unconfounded cases of NSF: (**Only Group II Agents should be utilized for research studies**)

- Gadobenated dimeglumine (MultiHance-Bracco Diagnostics)
- Gadobutrol (Gadavist-Bayer HealthCare Pharmaceuticals; Gadovist in many countries)
- Gadoterate acid (Dotarem-Guerbet)
- Gadoteridol (ProHance- Bracco Diagnostics)

Group III: Agents for which data remains limited regarding NSF risk, but for which few, if any unconfounded cases of NSF have been reported:

- Gadoxetate disodium (Eovist- Bayer HealthCare Pharmaceuticals; Primovist in many countries)

Last Revised: May 17, 2018 MRI Safety Committee

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