Updated February 2, 2017

Policies Related to Administration of Gadolinium Containing Contrast Agents to Human Subjects in the Ahmanson-Lovelace Brain Mapping Center

Investigators contemplating human administration of gadolinium containing compounds are strongly encouraged to review the American College of Radiology's Manual on Contrast Media (https://www.acr.org/quality-safety/resources/contrast-manual) which contains pertinent information regarding risks and safety.

1. A physician who has been formally authorized by the Center director must be present in the building at the time of administration of gadolium containing contrast agents and for at least 15 minutes following administration. If the physician is not physically present in the scanner suite at the time of administration, the person administering the contrast agent must verify the physican is in the building and will remain available for the 15 minutes following administration. Necessary conditions to be authorized to serve as the physician for gadolinium adminstration include:

A. A current license to practice medicine in the state of California
B. Up-to-date MR safety certification in the Brain Mapping Center
C. Completion of ALBMC training regarding treatment of gadolinium related complications

2. Gadolinium containing contrast agents may be administered only by individuals whose qualifications to do so have been reviewed and approved by the Center director.

3. Before the study, the person administering the gadolinium containing contrast agent should confirm with Center staff that the drugs and supplies for treating contrast related complications are up to date and should personally confirm the current location of these drugs and supplies.

4. Unless an exception has been explicitly authorized by the Center director, subjects must be screened to assure that gadolinium containing contrast agents are not administered to:

A. individuals who have had prior complications associated with prior gadolinium containing contrast agents
B. individuals who have moderate or greater renal impairment (adequate renal function must be documented in all subjects by laboratory measurement within 6 weeks of administration demonstrating eGFR* 60 mL/min/1.73 m2 or greater)
C. women who are breastfeeding
D. women who are pregnant or who might be pregnant
E. individuals under the age of 18

Exceptions will only be considered when the associated risks have been explicitly addressed in the associated IRB submission and a determination made by the IRB that

the risks are justified. Even with IRB approval, review and additional approval of the Center director is required.

5. In view of the recent FDA safety announcement regarding the persistence of gadolinium-based contrast agents in the brain (http://www.fda.gov/Drugs/DrugSafety/ucm455386.htm) even in subjects with normal renal function, evidence that the IRB has been made aware of this issue must be provided to the BMC before IRB materials related to gadolinium administration will be approved.

6. Most gadolinium containing compounds are not currently FDA approved for administration by power injector. Where not FDA approved, use of a power injector for administration would require specific IRB approval, and the IRB materials would need to make clear that this is not an FDA approved administration strategy. Any study proposing to use a power injector to administer gadolinium containing compounds must be reviewed and approved by the Center director who would likely elect to implement new safety policies specific to power injection at that time. Ample advance notice should be provided to the Center director to minimize delays.

7. Administration of doses that exceed FDA approved dosing must be justified in IRB materials and also require explicit approval of the Center director. The links below provide the FDA approved dosing information.

gadofosveset trisodium (Ablavar)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021711s003lbl.pdf
gadoterate meglumine (Dotarem)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204781s000lbl.pdf
gadoxetate disodium (Eovist)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022090s008lbl.pdf
gadobutrol (Gadavist)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/201277s003lbl.pdf
gadopentetate dimeglumine (Magnevist)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/019596s056,021037s029lbl.pdf
gadobenate dimeglumine (MultiHance)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021357s009lbl.pdf
gadodiamide (Omniscan)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022066s007,020123s043lbl.pdf
gadoversetamide injection (OptiMARK)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020937s02420975s252097 6s26lbl.pdf
gadoteridol (ProHance)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020131s024lbl.pdf

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*eGFR is the estimated glomerular filtration rate and is based on the subject's serum creatinine, age, sex and race using the following Modification of Diet in Renal Disease (MDRD) Study equation:

eGFR (mL / min/1.73 m2) = 175 × (serum creatinine in mg/dl)^–1.154 × (age in years)^–0.203 ×
(0.742 if female) × (1.212 if African American)

If only a serum creatinine is available on the laboratory report, the eGFR can be calculated using the on-line calculator at https://www.niddk.nih.gov/health-information/health-communication-programs/nkdep/lab-evaluation/gfr-calculators/adults-conventional-unit/Pages/adults-conventional-unit.aspx