SOP Number **OCMR_009**

SOP Title **The use of gadolinium-based contrast agents (GBCA)**

	NAME	TITLE	SIGNATURE	DATE
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1. PURPOSE

The purpose of this SOP is to describe the procedures to be followed when gadolinium based contrast agents (GBCA) are administered for magnetic resonance imaging in OCMR.

2. SCOPE

This SOP applies to all patients and clinical research participants where GBCA are to be administered at OCMR.

3. INTRODUCTION

Nephrogenic systemic fibrosis (NSF) involves fibrosis of the skin, joints, eyes and internal organs and is potentially fatal. It has been directly linked to the administration of gadolinium based contrast agents in patients with reduced renal function. The European Medicines Agency has classified GBCA into three risk groups; low, medium and high based on their chemical composition and ionic structure. In OCMR only GBCA with a low risk of causing nephrogenic systemic fibrosis will be used, unless specifically authorised by the safety committee.

4. RESPONSIBILITIES

Investigator or healthcare professional administering GBCA

To ensure that that these guidelines are followed so that all patients and/ or participants have been adequately assessed for renal impairment prior to the administration of GBCA.

5. SPECIFIC PROCEDURES

5.1 All patients/ participants who are to be given GBCA need to be screened for history of renal disease

Those with the following criteria require a laboratory blood result for serum creatinine/ eGFR **within the last 6 months**.

- Age >65 years
- Hypertension
- Diabetes
- History of renal disease
- Any acutely unwell patients - those admitted to hospital for acute care must have a creatinine measurement performed as close as possible to the scan, ideally within 24 hours (especially those with fluctuating renal function), but **no more than 3 days** prior to the scan. All others may receive GBCA without measurement of creatinine

The Cockcroft – Gault formula is used to calculate eGFR in OCMR.

5.2 **Obtaining a creatinine measurement**

Whenever possible information on creatinine/ eGFR should be requested before the scan is scheduled, so that it is available when the patient arrives. If creatinine/ eGFR is unavailable on the day of the scan creatinine can be measured using the iSTAT laboratory test kit. This provides an immediate result, eGFR can then be calculated.

5.3 **Action when creatinine measurement is obtained**

- **eGFR >30ml/min** (renal disease stage 1-3): All patients/ participants can receive GBCA.
- **eGFR <30ml/min** (stage 4 and 5 kidney failure)

  Clinical patients with strong indications for the scan, outweighing the small risk of NSF may receive GBCA. A risk-benefit assessment must be conducted for each patient and patient consent obtained. If GBCA is administered to patients already on dialysis, dialysis should occur as soon as possible thereafter.

  Research participants with an eGFR <30ml/min should not receive GBCA.

5.4 All patients will receive GBCA with a low risk of causing NSF. Research studies proposing to use anything other than a low risk GBCA must gain approval from the OCMR safety committee.

5.5 All studies which involve the use of GBCA need to incorporate these guidelines into the study protocol.

5.6 For dosage and administration advice please refer to OCMR Work Instruction 001 which is available on the website (http://www.ocmr.ox.ac.uk/documents).

5.7 Use of GBCA is also contraindicated in patients who have had or are awaiting liver transplantation.

5.8 If an abnormal creatinine result is found refer to the relevant incidental findings SOPs (http://www.ocmr.ox.ac.uk/documents).

6. INTERNAL AND EXTERNAL REFERENCES

OCMR work instruction 001 – Gadolinium use in CMR

OCMR SOP_001 MR Scanning

OCMR SOP_ 005 Dealing with cardiac incidental MRI scan findings

OCMR SOP_006 Dealing with non-cardiac incidental MRI scan findings

A creatinine/ eGFR calculator is available at: http://nephron.com/cgi-bin/CGSI.cgi

7. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
OCMR_009	**Sept 2016**	**New Version**	**OCMR Cardiac_003**