

NSsaFe study: Observational study on the incidence of nephrogenic systemic fibrosis in renal impaired patients following gadoterate meglumine administration.

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Purpose: The link between Nephrogenic Systemic Fibrosis (NSF) and gadolinium-based contrast agents (GBCAs) was made in 2006^{1,2}. High doses of GBCAs, and possibly use of linear nonionic GBCAs, contribute to increased risk of NSF. Patients with severely impaired kidney function and concurrent proinflammatory condition have an increased risk to develop NSF. The incidence of NSF after injection of GBCAs must be determined not only in patients with severe renal impairment, but also in patients with moderate renal impairment in order to provide an estimate covering a large population of renal impaired patients. Therefore, the main purpose of this study is to prospectively estimate the incidence of NSF in patients with moderate to severe renal impairment after administration of gadoterate meglumine.

Methods: An ongoing worldwide post-marketing study (PMS) is conducted to collect safety data in 1,000 patients (adults and children) with moderate to severe and end stage renal impairment, scheduled to undergo a routine contrast-enhanced magnetic resonance (MR) imaging using gadoterate meglumine (Dotarem®). For each patient, risk factors at inclusion, indications for MR imaging, and occurrence of adverse events are recorded and 3 follow up visits (between 3 months and 27 months after MRI) are performed in order to detect any suspicion or occurrence of NSF.

Results: As of September 10, 2012, the cut-off date for the interim safety analysis, this ongoing PMS included data on 163 patients (mean age: 70.5 years (range: 21-92); male: 59.5%). The mean eGFR was 37.0 ml/min/1.73m² (range: 4.0-59.0) including 64.4% of moderate, 20.9% of severe, 11.7% of end stage renal insufficiency and 2.5% of kidney transplanted patients. CNS MR examinations accounted for nearly 30%. The first follow-up visit was done for 35 patients and no NSF occurred. Only 1 patient (0.6%) had two serious adverse events not related to gadoterate meglumine.

Discussion: GBCAs have recently been associated with the development of Nephrogenic Systemic Fibrosis and should be used with caution in patients with renal failure.

Conclusion: This interim safety analysis already confirms the very good safety profile of gadoterate meglumine in renal impaired patients.

References:

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