

## Prevalence of Nephrogenic Systemic Fibrosis (NSF) in dialysis patients: Final results of the Pro-FINEST study

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### PURPOSE

NSF is a cutaneous and systemic disorder characterized by widespread tissue fibrosis. Although the exact physiopathology is still unknown, emergence of NSF has been strongly linked with gadolinium based contrast media (GBCA). Therefore recommendations on the use of GBCA in renal impairment patients were published by the different drug agencies worldwide. The Pro-FINEST study was supported by the French societies of dermatology, nephrology and radiology, and the university seminars of nephrology. The study was sponsored by the French drug agency (ANSM) and the French society of radiology. It aims at determining the prevalence of NSF after a Magnetic Resonance Imaging (MRI) examination, with or without GBCA, in chronic dialysis patients.

### METHODS

Pro-FINEST is a prospective multicentric study performed in 109 dialysis centers. It aims at evaluate the prevalence of NSF in adult (> 18 years old) and chronic dialysis ( $\geq 3$  months) patients after a MRI examination prescribed between the 15<sup>th</sup> of January 2009 and the 31<sup>st</sup> of May, with or without GBCA injection. The protocol is a 3 steps process mainly based on a patient form intended to detect skin events (SE) suggestive of NSF. Further investigations are planned in case of SE. When a NSF diagnosis is confirmed, an ancillary study is scheduled, with random selection of 4 patients (same gender, dialysis technique, centre, GBCA and without any SE after MRI).

### RESULTS

During 26 months, 571 patients have been included (109 centres): mean age 63.3 years, 58.5% males. 50.3% received GBCA, 93.4% a macrocyclic GBCA 88.9% Gadoterate. Almost 76% of the patients who underwent an injected MRI received a right dose of GBCA. 22 patients reported a SE but dermatological diagnoses did not report any evidence of NSF. Over the same period, no case of NSF has been reported to the Drug Safety Department of the French drugs agency.

### CONCLUSION

No case of NSF has been reported in 571 dialysis patients among whom the majority received a macrocyclic GBCA, mainly gadoterate. The Pro-FINEST study reassures clinicians about the appropriate use of macrocyclic gadolinium-based contrast agents in renal insufficiency patients including those in dialysis. The respect of the recommendations for use of GBCA tends to reduce the prevalence of NSF including in a at risk group.