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Sviluppo di Fibrosi Nefrogenica Sistemica (NSF) dopo somministrazione di mezzo di contrasto (mdc) con gadolinio in corso di Risonanza Magnetica Nucleare (RMN)

In data 23 Luglio 2009, l'Endocrine Society ha segnalato l'eventuale possibilità di sviluppo di una Fibrosi Nefrogenica Sistemica (NSF) dopo somministrazione di Gadolinio in corso di RMN, ma tale evenienza potrebbe verificarsi solamente in pazienti che sono già affetti da problematiche renali.
Questi pazienti hanno manifestato problematiche cutanee, con perdita di elasticità e movimento della cute, e conseguenti lacerazioni.
La FDA aveva inviato un report di possibili effetti collaterali legati alla somministrazione di Gadolinio nel 2006 e nel 2007.
Negli USA 517 pazienti hanno portato in giudizio 5 ditte farmaceutiche che producono i mezzi di contrasto che contengono Gadolinio.
Si raccomanda ai pazienti che devono essere sottoposti a RMN di eseguire una valutazione della funzionalità renale prima di eseguire tale indagine: il livello di filtrato glomerulare al di sotto del quale il rischio aumenta corrisponde a una clearance della creatinina di 30 ml/minuto.

Si allega il link ipertestuale della Società Italiana di Radiologia Medica (SIRM), della Società Italiana di Nefrologia e della Associazione Italiana di Neuroradiologia sulla Fibrosi nefrogenica sistemica: raccomandazioni per l'uso degli agenti di contrasto a base di gadolinio.
http://www.sirm.org/it/linee-guida/doc_download/33-fibrosi-nefrogenica-sistemica

Patients diagnosed with NSF after being injected with contrast-agent. File class-action suit against five drug companies

Rhode Island's WPRI News (7/14, White) reports that "in a massive lawsuit," 517 plaintiffs are suing "pharmaceutical companies that make certain dyes used for magnetic resonance imaging (MRI)." They were "diagnosed with nephrogenic systemic fibrosis (NSF) after being injected with a contrast-agent made with gadolinium." While "patients with healthy kidneys simply flush the gadolinium out," those "with NSF describe their skin turning wood-like, eventually cracking." The FDA "issued a warning in 2006 and 2007 not to administer the drug to those with kidney problems," but "gadolinium is still used in routine MRIs." The class-action suit "against five pharmaceutical companies that make gadolinium-based contrasting agents is getting larger as more and more are diagnosed with NSF." Some claim that they were "never warned about the possible side-effect because the medical community was in the dark at the time."

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WARWICK, R.I. (WPRI) - A Warwick woman has joined 516 other plaintiffs in a massive lawsuit against pharmaceutical companies that make certain dyes used for magnetic resonance imaging (MRI).
The woman, who did not want to be identified, was diagnosed with nephrogenic systemic fibrosis (NSF) in 2006 after being injected with a contrast-agent made with gadolinium. It's a rare disease that affects people with renal failure, such as kidney disease.
The contrast-agent, or dye, is used during an MRI to help technicians and doctors examine tissue. Patients with healthy kidneys simply flush the gadolinium out. People diagnosed with NSF, however, describe their skin turning wood-like, eventually cracking. The disease can move to organs where it can be fatal.
"It's awful," says Dr. Leslie Robinson-Bostom, an Associate Professor of Dermatology at Brown University. "Some patients will have a rapidly progressive course, where they're fine. Three weeks later they're wheelchair-bound."
The attorney for the Warwick woman, Patrick Barry of Providence law firm Morowitz and Barry, tells The Target 12 Investigators his client's condition got so bad, she had to have a finger amputated.
"Imagine if you're wearing very tight gloves when you tried to bend your fingers," Barry says. "It's very tough to do and the skin will actually break down on the knuckles."
Gadolinium is still used in routine MRI's, but the U.S. Food and Drug Administration issued a warning in 2006 and 2007 not to administer the drug to those with kidney problems. The products are marketed as Magnevist, MultiHance, Omniscan, OptiMARK and ProHance, according to the FDA's website.
Now a class-action lawsuit against five pharmaceutical companies that make gadolinium-based contrasting agents is getting larger as more and more are diagnosed with NSF. Barry says his client was never warned about the possible side-effect because the medical community was in the dark at the time.
"We want to uncover exactly what the manufacturers knew and when," Barry says. "How much information did they have and what did they do with it?".
Barry says his client was injected with a dye made by G.E. Healthcare. Company spokesperson Ryan Fitzgerald issued a statement that reads in part: "...no definitive causal relationship between the administration of gadolinium-based contrast agents to patients with moderate to severe renal impairment and NSF has ever been found."
But Barry says the FDA researched 75 patients who were diagnosed with NSF and found each one had been administered gadolinium before their MRI.
Dr. Robinson-Bostom says she has diagnosed 11 patients from Rhode Island with NSF. "We know that 10 of them definitely received gadolinium dye for MRI's before they developed the disease," Dr. Robinson-Bostom says.
She says if caught early enough, NSF can be treated, but the prognosis is often poor.
Medical experts say healthy people have nothing to worry about when going in for an MRI and receiving a dye. But those with kidney problems need to talk to a doctor.