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EMA reviewing gadolinium contrast agents used in MRI scans

Review to consider evidence on gadolinium accumulation in brain tissue

The European Medicines Agency (EMA) has started a review of the risk of gadolinium deposition in brain tissue following the use of gadolinium contrast agents in patients having magnetic resonance imaging (MRI) scans.

Gadolinium contrast agents are diagnostic products that may be given to patients before or during MRI scans to help doctors obtain better images of organs and tissues. After administration, gadolinium agents are mostly eliminated via the kidneys but studies indicate that deposits can build up in some body tissues, including in the liver, kidney, muscle, skin and bone.

Recently, a number of publications have reported that gadolinium contrast agents also accumulate in brain tissue.[1-7] In January 2016, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) reviewed these publications. Although no adverse effects relating to gadolinium brain deposition have been reported to date, the PRAC will carry out an in-depth review of the risk of brain deposits and of the overall safety of these products.

The PRAC's recommendations will be sent to Committee for Medicinal Products for Human Use (CHMP), which will issue the Agency's final opinion.

More about the medicine

Gadolinium contrast agents contain gadolinium, which is used as a 'contrast enhancer' to help make body tissues more visible on the scan.

This review covers agents containing the following active substances: gadobenic acid, gadobutrol, gadodiamide, gadopentetic acid, gadoteric acid, gadoteridol, gadoversetamide and gadoxetic acid.

Most gadolinium-containing contrast agents have been authorised nationally in the European Union (EU). OptiMARK (gadoversetamide) is currently the only centrally authorised gadolinium contrast agent in the EU.

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More about the procedure

The review of gadolinium contrast agents has been initiated at the request of the European Commission, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations.

The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt a final opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.

A previous EMA review of gadolinium contrast agents in 2010 evaluated the risk of nephrogenic systemic fibrosis (NSF).

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