Gadolinium-containing contrast agents

PRAC confirms restrictions on the use of linear gadolinium agents

Benefit-risk balance of certain linear gadolinium agents no longer favourable

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has confirmed its previous conclusion from March 2017 that there is convincing evidence of gadolinium deposition in brain tissues following use of gadolinium contrast agents.

No specific conditions linked to gadolinium deposition in the brain have been identified, but the clinical consequences are unknown.

As a result of the review, the PRAC recommends that the intravenous linear agents gadoxetic acid and gadobenic acid should only be used for liver scans in the situations where they meet an important diagnostic need. In addition, gadopentetic acid should only be used for joint scans as the gadolinium concentration in the formulation used for joint injections is very low.

All other intravenous linear agents (gadodiamide, gadopentetic acid and gadoversetamide) should be suspended in line with the PRAC's March 2017 recommendation.

Another class of gadolinium agents known as macrocyclic agents (gadobutrol, gadoteric acid and gadoteridol) are more stable and have a lower propensity to release gadolinium than linear agents. These can continue to be used in their current indications but in the lowest doses that enhance images sufficiently and only when unenhanced body scans are not suitable.

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

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Name	Language	First published	Last updated
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