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Results of the QUANTI CNS study: Efficacy and Safety of gadoquatrane in patients undergoing contrast-enhanced MRI of the CNS at reduced Gadolinium dose compared to macrocyclic GBCAs.

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Purpose

Gadoquatrane is a novel tetrameric macrocyclic gadolinium (Gd)-based contrast agent (GBCA) that exhibits high relaxivity. This characteristic allows for a reduction in the Gd dose for contrast-enhanced (CE) MRI while maintaining a similar signal intensity level compared to current macrocyclic GBCAs. The QUANTI CNS study is a phase 3 trial investigating efficacy and safety of gadoquatrane, at a dose of 0.04 mmol Gd/kg body weight (bw) compared to 0.1 mmol Gd/kg bw of macrocyclic GBCAs (gadobutrol, gadoterate meglumine, and gadoteridol) in CE-MRI of the central nervous system (CNS) in adults.

Materials and Methods

QUANTI CNS is a multicenter, randomized, prospective double-blind, cross-over study, conducted between July 2023 and May 2024 in 15 countries. Adult patients with known or suspected CNS pathology underwent two CE-MRIs, one with gadoquatrane and the other with a comparator GBCA, administered in random order with a washout period of 3 to 14 days in between. MRIs were evaluated in a blinded independent central review by three neuroradiologists. Safety parameters, such as adverse events and laboratory parameters, were assessed for both MRI periods.

Results

Out of 303 patients receiving at least one contrast administration, 294 completed both MRIs. Among these participants, 58% were female, and the mean age was 55.5 years. The study met its primary objectives by

demonstrating that combined (pre-and post-contrast) gadoquatrane MRI is non-inferior to combined comparator MRI and superior to pre-contrast MRI, based on the three visualization parameters: contrast enhancement, delineation, and morphology.

The mean scores vs. combined comparator MRI were similar for all three parameters and three readers, with differences close to zero and below the non-inferiority margin of 0.35. Combined gadoquatrane MRI demonstrated significant improvements in all visualization parameters compared to pre-contrast images ($p<0.0001$) for all three readers. The key secondary endpoints, sensitivity and specificity for the detection of lesions, were also non-inferior to comparator MRI.

The safety profile (adverse events (AEs), serious AEs, safety parameters) was similar for gadoquatrane and comparators.

Conclusion

Gadoquatrane at a dose of 0.04 mmol Gd/kg bw, which corresponds to a 60% reduced Gd dose compared to GBCA at 0.1 mmol Gd/kg bw, is non-inferior for CE-MRI of the CNS with a similar safety profile, and is superior to pre-contrast MRI.

Limitations: The limitation of the study is application of gadoquatrane in specific protocols that were not evaluated due to study design requirements.

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Disclosure:

Authors SH, AL, MK, GS, BHM, and PP are employees of Bayer AG, Berlin, Germany

and have indirect or direct financial interest in some of the products under investigation

or subject matter discussed in the manuscript.

References

None

Figures

Upper left: forest plot comparison vs. combined comparator MRI

Upper right: forest plot comparison vs. pre-contrast MRI

Lower left: example, brain lesion, meningioma

Lower right: example, spine malignant lesion