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DISCO: Safety, Tolerability and Diagnostic performance of 64Cu-SARTATE compared to 68Ga-DOTATATE in patients with known or suspected neuroendocrine tumors.

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BACKGROUND

Diagnostic imaging is critical in the diagnosis, staging, management, and follow-up of neuroendocrine tumors (NETs). Characteristics of ^{64}Cu-SARTATE may provide advantages over existing imaging, including ^{68}Ga-DOTATATE, because of its longer half-life and potential to detect additional disease.

METHODS

This Phase I/II study assessed the safety and efficacy of ^{64}Cu-SARTATE (200 MBq) in participants with known or suspected gastroenteropancreatic (GEP)-NETs. Participants were assessed with ^{68}Ga-DOTATATE PET/CT within 35 days prior to ^{64}Cu-SARTATE administration, with the ^{64}Cu-SARTATE PET/CT performed at 4 ± 1 hrs (same-day) and 20 ± 4 hrs (next-day) post-injection. Scans were assessed by 2 independent blinded central readers. Discordant lesions (lesions present on only one scan, either ^{64}Cu-SARTATE or ^{68}Ga-DOTATATE) were subsequently evaluated by an independent assessor against the standard of truth (biopsy and/or conventional imaging, collected during a follow-up period of up to 12-month). Per-lesion sensitivity, specificity, and lesion detection rate of both ^{64}Cu-SARTATE timepoints were compared to ^{68}Ga-DOTATATE among those with discordant findings. Safety was assessed via vital signs, laboratory tests, physical examinations, ECGs and adverse event (AE) reporting.

RESULTS

45 participants were enrolled , 41 with known NETs and 4 with suspected NETs, across 4 sites in Australia. The number of lesions detected across readers ranged from 393-488 with ^{64}Cu-SARTATE (both timepoints) and 186-265 for ^{68}Ga-DOTATATE. 93.5% of 230-251 discordant lesions identified were detected on ^{64}Cu-SARTATE, while only 6.5% of discordant lesions were identified on ^{68}Ga-DOTATATE. Average lesion-level sensitivity of evaluable discordant lesions was 94.7% (95% CI 65.1, 99.5) for ^{64}Cu-SARTATE (across both timepoints) compared to 5.4% (95% CI 0.5, 34.9) for 68Ga-DOTATATE. Average sensitivity on same-day ^{64}Cu-SARTATE PET/CT was 95.1% (95% CI 80.1, 98.6) and 94.3% (95% CI 65.1, 99.5) on next-day PET/CT. Average specificity was 62.5% (95% CI 3.1, 99.5) for ^{64}Cu-SARTATE (across both timepoints) and 37.5% (95% CI 0.5, 96.9) for ^{68}Ga-DOTATATE, this was impacted by the low number of discordant lesions identified by ^{68}Ga-DOTATATE. Seven (15.6%) participants experienced ^{64}Cu-SARTATE-related AEs; 8 were Grade 1, 1 was Grade 2, mostly resolving within 2 days. No serious treatment-emergent AEs were observed.

CONCLUSIONS

^{64}Cu-SARTATE was found to be safe and well-tolerated. In participants with known or suspected GEP-NETs, ^{64}Cu-SARTATE lesion detection outperformed that of ^{68}Ga-DOTATATE. The improved diagnostic performance of ^{64}Cu-SARTATE has important clinical implications for the identification of GEP-NET lesions to inform treatment pathways. A phase III study of ^{64}Cu-SARTATE in NETs is being planned to build on these results.

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