

## **DIAGNOSTIC EFFECTIVENESS OF IOFLUPANE I123 INJECTION (DATSCAN) SPECT IN PATIENTS WITH MOVEMENT DISORDERS AND/OR DEMENTIA**

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**Background:** Early and accurate diagnosis of movement disorders and dementia is critical to ensuring optimal clinical management. Ioflupane I 123 injection (DaTSCAN™ or ioflupane (<sup>123</sup>I)) is approved to visualize loss of striatal dopamine transporter in a subset of patients with dementia and movement disorders. **Methods:** Three Phase 3 and one Phase 4 clinical trials were pooled to determine the overall sensitivity and specificity of ioflupane (<sup>123</sup>I) images in detecting or excluding a striatal dopaminergic deficit (SDD), which is associated with Parkinsonian syndrome and dementia with Lewy bodies. Patients with either a movement disorder or dementia, and healthy volunteers were administered ioflupane (<sup>123</sup>I). Images were assessed by panels of 3-5 blinded experts and/or on-site nuclear medicine physicians, classified as normal or abnormal, and compared with clinical diagnosis (reference standard) to determine sensitivity and specificity.

**Results:** Pooling the four studies, 928 subjects were enrolled, 849 were dosed, and 764 completed their study. Across all studies, when images were assessed by on-site readers, ioflupane (<sup>123</sup>I) diagnostic effectiveness had an overall (95% CI) sensitivity of 91.9% (88.7 to 94.5) and specificity of 83.6% (78.7 to 87.9). When reads were conducted blindly by a panel of independent experts, the overall sensitivity was 88.7% (86.8 to 90.4) and specificity was 91.2% (89.0 to 93.0).

**Conclusions:** In this pooled analysis, the visual assessment of ioflupane (<sup>123</sup>I) images provided high levels of sensitivity and specificity in detecting the presence/absence of an SDD. Ioflupane (<sup>123</sup>I) imaging has the potential to improve diagnostic accuracy in patients with signs and symptoms of a movement disorder and/or dementia.