

Official Title: DPP4 inhibitor on post-stroke cognitive impairment in ischemic stroke patients with type 2 diabetes mellitus (DISC-DM): multicentre, double blind, randomised, placebo controlled trial

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Efficacy analyses were primarily conducted using the intention-to-treat (ITT) dataset, with additional per-protocol (PP) analyses performed to compare changes in Montreal Cognitive Assessment (MoCA) scores. A mixed-effects model was used to evaluate the effect of DPP4 inhibitor treatment on changes in cognitive function scores. The SAS PROC MIXED procedure was applied to obtain the point estimates and standard errors for the intervention group, and to test the difference in treatment effects between the intervention and control groups. All P values were 2-tailed, and a significance level of 0.05 was used. Data analyses were performed using SAS, version 9.4 (SAS Institute, Inc, Cary, NC).

The primary outcome is the change in MoCA score from baseline to 6 months after intervention. Based on previous studies, the 6-month MoCA score in patients with ischemic stroke is 22 points. After DPP4 inhibitors intervention, the two groups are expected to differ by 2 points in MoCA score, with the intervention group having a 6-month MoCA score of 24 points and a standard deviation of 5 points. To achieve 90% statistical power (two-sided $\alpha = 0.05$), 264 patients will be required. Considering a 15% loss to follow-up, the estimated total sample size will be 312 patients.