Trial **Intravenous Odatroltide for Acute Ischemic Stroke Within 24 Hours of Onset: A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study**

Clinical ID NCT04091945

Executive Summary

Key finding : Intravenous odatroltide was well tolerated and might improve neurological outcomes when administered within 24 hours of ischaemic stroke onset.

Odatroltide is a small artificially synthesized tripeptide compound engineered to target thrombus formation. It was designed from a human fibrinogen sequence to increase thrombolytic activity and restore flow in occluded blood vessels. It can function as an antioxidant and is safe and well-tolerated in healthy human volunteers.

Investigators enrolled patients following a recent ischemic stroke event in the trial. Whilst mortality and additional ischemic events occurred, this was not statistically significant given the low enrolment. Neurological assessments at 0, 30, and 90 days indicated improvements in the intervention arm. A more extensive phase 3 trial is needed to confirm a probable benefit.

Stroke (+2 events) and mortality (1 event each) were observed in the intervention and control arms over seven days. No other serious adverse events, e.g., bleeding, were reported. Hypertension and constipation were the most commonly noted side effects.

Population	US and Taiwan-based (n=24)
Intervention	0.025mg/kg intravenous Odatroltide.
Inclusion Criteria	18-90 years, within 24 hrs of an ischemic stroke event
Exclusion Criteria	Hemorrhagic stroke, previous stroke, surgery
Controls	placebo controls randomized 2:1
Outcomes	
Primary	Occurrence of symptomatic intracranial hemorrhage (sICH) within 36 hrs of treatment, followed for 90 days.
Secondary	Safety - bleeding, recurrent stroke, mortality

Reference

Chao AC, Lee TH, Pettigrew LC, et al. Intravenous Odatroltide for Acute Ischemic Stroke Within 24 Hours of Onset: A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study. Drug Des Devel Ther. 2024;18:2033-2042. Published 2024 Jun 6. doi:10.2147/DDDT.S460831