June 12, 2025

Tirofiban with Sequential Dual Antiplatelet Therapy versus Dual Antiplatelet Therapy Alone in Mild Acute Ischemic Stroke (TiMIS): A Multicenter, Open-Label, Blinded-Endpoint, Parallel-Controlled, Randomized Clinical Trial

Statistical Analysis Plan

Efficacy analyses were primarily performed on the per-protocol (PP) dataset, with additional intention-to-treat (ITT) analyses conducted for comparisons of event rates. Continuous variables were assessed for normality using the Kolmogorov–Smirnov test. Data that were normally distributed are presented as mean ± standard deviation (SD) and were compared using independent samples t-tests, while data that were not normally distributed are reported as median (interquartile range [IQR]) and were analysed using Wilcoxon rank-sum tests. Categorical data were compared using chi-squared tests, while ordinal data were analysed using non-parametric tests. All analyses were conducted using SAS or R software, with a two-sided p value of less than 0.05 being considered statistically significant. This superiority trial used a 90-day excellent functional outcome (mRS 0–1) as the primary endpoint. Assuming rates of 68% (control group) versus 78% (tirofiban sequential DAPT group), with an absolute difference of 10%, a sample size of 580 participants (290 per group) was calculated using PASS software, accounting for a 10% dropout rate and 1:1 block randomisation.