HLM051

Rationale MultiStem® (HLM051) is one of the promising allogenic cell products for acute ischemic stroke with strong evidence. A previous phase 2 randomized, double-blind, placebo-controlled, multicenter dose-escalation trial showed the safety of MultiStem® for acute ischemic stroke, with a time window beyond that of rt-PA and endovascular thrombectomy. We aim to obtain stronger evidence and to show the efficacy of the MultiStem® for treatment of ischemic stroke. Sample size Estimated sample size is 220 (110 patients per group), which has 90% power at 5% significance level. Methods and design TREASURE is a randomized, double-blind, placebo-controlled, multicenter phase 2/3 trial. The trial will be done at 31 medical centers in Japan. Patients with acute ischemic stroke including motor or speech deficit defined by a National Institution of Health Stroke Scale (NIHSS) score of 8-20 at baseline will be randomized 1:1 to receive a single intravenous infusion of MultiStem® or placebo within 18-36 h of stroke onset. Study outcomes Primary outcome in this study is the proportion of patients with an excellent outcome at day 90 defined by the functional assessment. Trial registration ClinicalTrials.gov (NCT02961504). Conclusion The TREASURE trial will provide a novel treatment option and expand the therapeutic window for patients with stroke if the results are positive [1].

1)
Osanai T, Houkin K, Uchiyama S, Minematsu K, Taguchi A, Terasaka S. Treatment evaluation of acute stroke for using in regenerative cell elements (TREASURE) trial: Rationale and design. Int J Stroke. 2017 Jan 1:1747493017743057. doi: 10.1177/1747493017743057. [Epub ahead of print] PubMed PMID: 29134924.