



Congratulations to MACC collaborator, Dr. Venketasubramanian Narayanaswamy for winning the best paper award at ASEAN 2015 Neuroscience conference, Singapore 30 – 31 July 2015

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CHinese Medicine NeuroAiD Efficacy on Stroke Recovery - Extension Study (CHIMES-E): A Multicenter Study of Long-Term Efficacy.

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Abstract

BACKGROUND: The CHinese Medicine NeuroAiD Efficacy on Stroke recovery (CHIMES) study was an international randomized double-blind placebo-controlled trial of MLC601 (NeuroAiD) in subjects with cerebral infarction of intermediate severity within 72 h. CHIMES-E (Extension) aimed at evaluating the effects of the initial 3-month treatment with MLC601 on long-term outcome for up to 2 years.

METHODS: All subjects randomized in CHIMES were eligible for CHIMES-E. Inclusion criteria for CHIMES were age ≥ 18 , baseline National Institute of Health Stroke Scale of 6-14, and pre-stroke modified Rankin Scale (mRS) ≤ 1 . Initial CHIMES treatment allocation blinding was maintained, although no further study treatment was provided in CHIMES-E. Subjects received standard care and rehabilitation as prescribed by the treating physician. mRS, Barthel Index (BI), and occurrence of medical events were ascertained at months 6, 12, 18, and 24. The primary outcome was mRS at 24 months. Secondary outcomes were mRS and BI at other time points.

RESULTS: CHIMES-E included 880 subjects (mean age 61.8 ± 11.3 ; 36% women). Adjusted OR for mRS ordinal analysis was 1.08 (95% CI 0.85-1.37, $p = 0.543$) and mRS dichotomy ≤ 1 was 1.29 (95% CI 0.96-1.74, $p = 0.093$) at 24 months. However, the treatment effect was significantly in favor of MLC601 for mRS dichotomy ≤ 1 at 6 months (OR 1.49, 95% CI 1.11-2.01, $p = 0.008$), 12 months (OR 1.41, 95% CI 1.05-1.90, $p = 0.023$), and 18 months (OR 1.36, 95% CI 1.01-1.83, $p = 0.045$), and for BI dichotomy ≥ 95 at 6 months (OR 1.55, 95% CI 1.14-2.10, $p = 0.005$) but not at other time points. Subgroup analyses showed no treatment heterogeneity. Rates of death and occurrence of vascular and other medical events were similar between groups.

CONCLUSIONS: While the benefits of a 3-month treatment with MLC601 did not reach statistical significance for the primary endpoint at 2 years, the odds of functional independence defined as mRS ≤ 1 was significantly increased at 6 months and persisted up to 18 months after a stroke.