Safety Profile of MLC601 (Neuroaid®) in Acute Ischemic Stroke Patients: A Singaporean Substudy of the Chinese Medicine Neuroaid Efficacy on Stroke Recovery Study

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Abstract

Background: Previous clinical trials have shown that Neuroaid® (MLC601), a traditional Chinese medicine, shows good tolerability and superiority over another traditional Chinese medicine in terms of neurological disability and functional outcome and thus may be beneficial as part of a poststroke rehabilitation program. The safety of MLC601 on hemostasis, hematology and biochemistry has been established in normal subjects and patients with nonacute stroke over a short treatment period. We assessed the safety of Neuroaid in patients with acute stroke treated for 3 months in a substudy of an ongoing randomized placebo-controlled trial. Methods: Laboratory tests (biochemical, hematological and electrocardiogram) were conducted at the month 3 follow-up, in addition to baseline tests. A total of 114 patients were recruited. As there were 13 dropouts, a total of 52 patients on MLC601 and 49 on placebo were available for analysis. Serious adverse events (SAEs) were also analyzed. Results: There were no statistically or clinically significant differences between treatment groups in biochemical, hematological or electrocardiogram tests at month 3, nor any statistically or clinically significant differences in the absolute and relative changes of the various parameters between baseline and 3 months. SAEs were similar and were those commonly seen in stroke patients. Conclusions: Longer-term laboratory safety data show no differences between MLC601 and placebo, confirming the safety of MLC601 in acute stroke patients receiving a 3-month treatment.

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