ARTEMIDA trial: Actovegin vs placebo

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BACKGROUND

Cognitive impairment affects more than 50% of stroke survivors. Studies of various pharmacological and non-pharmacological interventions for treatment and prevention of cognitive decline after stroke showed conflicting results; further trials are needed. Deproteinised haemoderivate (Actovegin) demonstrated multifaceted effects in animal models and promising efficacy in small clinical studies.

METHODS

ARTEMIDA (NCT01582854) was a 12-month, parallel-group, randomised, multicenter, double-blind, placebo-controlled trial to examine the effect of Actovegin treatment on PSCI over six months in subjects with ischaemic stroke admitted to 37 hospitals in 3 countries. Within seven days of stroke onset patients were randomized to Actovegin (2000 mg/day for up to 20 intravenous infusions followed by 1200 mg/day orally) or placebo for a six-month treatment period and a follow up for six months. The primary endpoint was the change from baseline in the Alzheimer’s Disease Assessment Scale (ADAS-Cog+). Secondary endpoints were Montreal Cognitive Assessment scale; dementia diagnosis (ICD-10); NIHSS; Barthel Index; EQ-5D; Beck Depression Inventory. Safety assessment included reported adverse events.

RESULTS

A total of 503 subjects were randomised. There was a significant difference in favor of Actovegin vs. placebo in the ADAS-Cog+ change from baseline at 6 months (LS mean difference -2.3 (95% CI -3.9, -0.7); p = 0.005). Several secondary outcome parameters confirmed superiority of Actovegin vs placebo. The safety experience was consistent with the known safety and tolerability drug profile. Ischaemic stroke was the most reported serious adverse event, with non-significantly higher number on Actovegin vs. placebo.

CONCLUSION

Actovegin improves cognitive outcomes in patients with ischemic stroke.