

Long-term effect of policosanol on the functional recovery of non-cardioembolic ischemic stroke patients: A one year study

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Introduction: Stroke is a leading cause of mortality and disability. Policosanol has been effective in brain ischemia models. Clinical studies suggested that policosanol (20 mg/day) + standard aspirin (AS) therapy had benefits versus placebo + AS given for 6 months to patients with recent non-cardioembolic ischemic stroke. The objectives of this study investigate whether policosanol, added to AS therapy within 30 days of stroke onset, is better than placebo + AS for the long-term recovery of non-cardioembolic ischemic stroke subjects.

Methods: This study was randomized, double-blind, placebo-controlled. Eighty patients with a modified Rankin Scale score (mRSs) 2 to 4 were randomized, within 30 days of onset, to policosanol/AS or placebo/AS, for 12 months. The primary outcome was mRSs reduction; the secondary outcome is the increase of Barthel Index (BI). Low-density lipoprotein-cholesterol (LDL-C) reduction and high-density lipoprotein-cholesterol (HDL-C) increase were collateral outcomes.

Results: Eighty patients (mean age: 69 years) were randomized. Policosanol/AS decreased significantly mean mRSs from the first interim check-up (1.5 months) ($p < 0.0001$ vs placebo/AS). The treatment effect did not wear off, even improved, after long-term therapy ($p < 0.0001$ versus placebo/

AS). More policosanol/AS (35/40, 87.5%) than placebo/AS (0/30, 0.0%) achieved mRSs ≤ 1 ($p < 0.0001$). Policosanol/AS increased significantly BI, lowered LDL-C and increased HDL-C versus placebo/AS. Treatments were well tolerated. There were 12 withdrawals, three due to fatal adverse events, all happened in the placebo/AS groups.

Conclusions: Long-term (12 months) administration of policosanol/AS given after suffering non-cardioembolic ischemic stroke was shown to be better than placebo/AS in improving functional outcomes at 3 and 12 months when used among patients with non-cardioembolic ischemic stroke of moderate severity.

Speaker Biography

Julio C Fernández is a Senior Investigator in Clinical Trials Unit, National Centre for Scientific Research, Havana city, Cuba. He has completed his BSc in Pharmaceutical Sciences from Havana University Cuba in 1996. He was awarded with PhD in Pharmaceutical Sciences in 2003. He has published more than 130 publications and presented more than 100 papers in various scientific events. His research interest mainly focuses on clinical trials phase I-IV of different natural products: Policosanol, Abexol, Prevenox, Palmex.

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