

Abstract

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Oral treatment with alpha-lipoic acid improves symptomatic diabetic polyneuropathy: the SYDNEY 2 trial.

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OBJECTIVE: The aim of this trial was to evaluate the effects of alpha-lipoic acid (ALA) on positive sensory symptoms and neuropathic deficits in diabetic patients with distal symmetric polyneuropathy (DSP).

RESEARCH DESIGN AND METHODS: In this multicenter, randomized, double-blind, placebo-controlled trial, 181 diabetic patients in Russia and Israel received once-daily oral doses of 600 mg (n = 45) (ALA600), 1,200 mg (n = 47) (ALA1200), and 1,800 mg (ALA1800) of ALA (n = 46) or placebo (n = 43) for 5 weeks after a 1-week placebo run-in period. The primary outcome measure was the change from baseline of the Total Symptom Score (TSS), including stabbing pain, burning pain, paresthesia, and asleep numbness of the feet. Secondary end points included individual symptoms of TSS, Neuropathy Symptoms and Change (NSC) score, Neuropathy Impairment Score (NIS), and patients' global assessment of efficacy.

RESULTS: Mean TSS did not differ significantly at baseline among the treatment groups and on average decreased by 4.9 points (51%) in ALA600, 4.5 (48%) in ALA1200, and 4.7 (52%) in ALA1800 compared with 2.9 points (32%) in the placebo group (all $P < 0.05$ vs. placebo). The corresponding response rates ($\geq 50\%$ reduction in TSS) were 62, 50, 56, and 26%, respectively. Significant improvements favoring all three ALA groups were also noted for stabbing and burning pain, the NSC score, and the patients' global assessment of efficacy. The NIS was numerically reduced. Safety analysis showed a dose-dependent increase in nausea, vomiting, and vertigo.

CONCLUSIONS: Oral treatment with ALA for 5 weeks improved neuropathic symptoms and deficits in patients with DSP. An oral dose of 600 mg once daily appears to provide the optimum risk-to-benefit ratio.

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