

Abstract

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Treatment of symptomatic diabetic polyneuropathy with the antioxidant alpha-lipoic acid: a meta-analysis.

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AIMS: To determine the efficacy and safety of 600 mg of alpha-lipoic acid given intravenously over 3 weeks in diabetic patients with symptomatic polyneuropathy.

METHODS: We searched the database of VIATRIS GmbH, Frankfurt, Germany, for clinical trials of alpha-lipoic acid according to the following prerequisites: randomized, double-masked, placebo-controlled, parallel-group trial using alpha-lipoic acid infusions of 600 mg i.v. per day for 3 weeks, except for weekends, in diabetic patients with positive sensory symptoms of polyneuropathy which were scored by the Total Symptom Score (TSS) in the feet on a daily basis. Four trials (ALADIN I, ALADIN III, SYDNEY, NATHAN II) comprised n=1258 patients (alpha-lipoic acid n=716; placebo n=542) met these eligibility criteria and were included in a meta-analysis based on the intention-to-treat principle. Primary analysis involved a comparison of the differences in TSS from baseline to the end of i.v. Treatment between the groups treated with alpha-lipoic acid or placebo. Secondary analyses included daily changes in TSS, responder rates (> or =50% improvement in TSS), individual TSS components, Neuropathy Impairment Score (NIS), NIS of the lower limbs (NIS-LL), individual NIS-LL components, and the rates of adverse events.

RESULTS: After 3 weeks the relative difference in favour of alpha-lipoic acid vs. placebo was 24.1% (13.5, 33.4) (geometric mean with 95% confidence interval) for TSS and 16.0% (5.7, 25.2) for NIS-LL. The responder rates were 52.7% in patients treated with alpha-lipoic acid and 36.9% in those on placebo (P<0.05). On a daily basis there was a continuous increase in the magnitude of TSS improvement in favour of alpha-lipoic acid vs. placebo which was noted first after 8 days of treatment. Among the individual components of the TSS, pain, burning, and numbness decreased in favour of alpha-lipoic acid compared with placebo, while among the NIS-LL components pin-prick and touch-pressure sensation as well as ankle reflexes were improved in favour of alpha-lipoic acid after 3 weeks. The rates of adverse events did not differ between the groups.

CONCLUSIONS: The results of this meta-analysis provide evidence that treatment with alpha-lipoic acid (600 mg/day i.v.) over 3 weeks is safe and significantly improves both positive neuropathic symptoms and neuropathic deficits to a clinically meaningful degree in diabetic patients with symptomatic polyneuropathy.

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