

Treatment of symptomatic diabetic peripheral neuropathy with the anti-oxidant alpha-lipoic acid. A 3-week multicentre randomized controlled trial (ALADIN Study).

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Abstract

Anti-oxidant treatment has been shown to prevent nerve dysfunction in experimental diabetes mellitus, thus providing a rationale of potential therapeutic value for diabetic patients. The effects of the **anti-oxidant alpha-lipoic acid (thioctic acid)** were studied in a 3-week multicentre, randomized, double-blind placebo-controlled trial (Alpha-Lipoic Acid in Diabetic Neuropathy; ALADIN) in 328 non-insulin-dependent diabetic patients with symptomatic peripheral neuropathy who were randomly assigned to treatment with intravenous infusion of alpha-lipoic acid using three doses (1200, 600, or 100 mg ALA) or placebo (PLAC). Neuropathic symptoms (pain, burning, paraesthesiae, and numbness) were scored at baseline and at each visit (days 2-5, 8-12, and 15-19) prior to infusion. In addition, the Hamburg Pain Adjective List, a multidimensional specific pain questionnaire, and the Neuropathy Symptom and Disability Scores were assessed at baseline and day 19. According to the protocol 260 (65/63/66/66) patients completed the study. The total symptom score in the feet decreased from baseline to day 19 by -4.5 +/- 3.7 (-58.6%) points (mean +/- SD) in ALA 1200, -5.0 +/- 4.1 (-63.5%) points in ALA 600, -3.3 +/- 2.8 (-43.2%) points in ALA 100, and -2.6 +/- 3.2 (-38.4%) points in PLAC (ALA 1200 vs PLAC: $p = 0.003$; ALA 600 vs PLAC: $p < 0.001$). The response rates after 19 days, defined as an improvement in the total symptom score of at least 30%, were 70.8% in ALA 1200, 82.5% in ALA 600, 65.2% in ALA 100, and 57.6% in PLAC (ALA 600 vs PLAC; $p = 0.002$). The total scale of the Pain Adjective List was significantly reduced in ALA 1200 and ALA 600 as compared with PLAC after 19 days (both $p < 0.01$). The rates of adverse events were 32.6% in ALA 1200, 18.2% in ALA 600, 13.6% in ALA 100, and 20.7% in PLAC. **These findings substantiate that intravenous treatment with alpha-lipoic acid using a dose of 600 mg/day over 3 weeks is superior to placebo in reducing symptoms of diabetic peripheral neuropathy, without causing significant adverse reactions.**

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