

Abstract

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A double-blind, randomised, controlled clinical trial of acetyl-L-carnitine vs. amisulpride in the treatment of dysthymia.

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AIM: Evaluation of the effect of acetyl-L-carnitine (ALCAR) vs. amisulpride measured by total Hamilton Depression Rating Scale score (HAM-D(21)) in patients with pure dysthymia (DSM IV).

METHODS: Two hundred and four patients were randomised and treated with ALCAR 500 mg b.i.d. or amisulpride 50 mg u.i.d. in a double-blind study, for 12 weeks.

RESULTS: A solid improvement of HAM-D(21) was observed in both treatment groups throughout the study. The results did not disclose statistically significant differences between treatments, although the confidence interval for the non-inferiority of the primary end-point exceeded the pre-established limit of 2 by 0.46 points. According to a non-inferiority margin of 3 (considered acceptable by recent published data) the primary end-point could have been fully satisfied. CDRS, MADRS and CGI, employed to further measure the clinical outcome, reported similar results in both treatment groups.

CONCLUSION: The greater tolerability of ALCAR is of clinical relevance considering the chronicity of dysthymia, which often requires prolonged treatment.

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