

Abstract

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Double-blind, multicenter trial comparing acetyl L-carnitine with placebo in the treatment of fibromyalgia patients.

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OBJECTIVE: Fibromyalgia (FMS) is a chronic syndrome characterized by widespread pain, troubled sleep, disturbed mood, and fatigue. Several analgesic strategies have been evaluated but the results are moderate and inconsistent. Antidepressant agents are now considered the treatment of choice in most patients. It has been recently suggested that FMS may be associated with metabolic alterations including a deficit of carnitine. In this multicenter randomized clinical trial we evaluated the efficacy of acetyl L-carnitine (LAC) in patients with overt FMS.

METHODS: One hundred and two patients meeting the American College of Rheumatology criteria for FMS were randomized into the study. The treatment consisted of 2 capsules/day of 500 mg LAC or placebo plus one intramuscular (i.m.) injection of either 500 mg LAC or placebo for 2 weeks. During the following 8 weeks the patients took 3 capsules daily containing either 500 mg LAC or placebo. The patients were seen during treatment after 2 (visit 3), 6 (visit 4) and 10 weeks (visit 5). The patients were also visited 4 weeks after treatment discontinuation (follow-up visit). Outcome measures included the number of positive tender points, the sum of pain threshold (kg/cm² or "total myalgic score"), the Short Form 36 (SF36), a 100 mm visual analog scale (VAS) for self-perceived stiffness, fatigue, tiredness on awakening, sleep, work status, depression, and muscular-skeletal pain, and the Hamilton depression scale.

RESULTS: The "total myalgic score" and the number of positive tender points declined significantly and equally in both groups until the 6th week of treatment. At the 10th week both parameters remained unchanged in the placebo group but they continued to improve in the LAC group with a statistically significant between-group difference. Most VAS scores significantly improved in both groups. A statistically significant between-group difference was observed for depression and musculo-skeletal pain. Significantly larger improvements in SF36 questionnaire were observed in LAC than in placebo group for most parameters. Treatment was well-tolerated.

CONCLUSION: Although this experience deserves further studies, these results indicate that LAC may be of benefit in patients with FMS, providing improvement in pain as well as the general and mental health of these patients.

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