

Abstract

Med Sci Monit. 2011 Jun 1;17(6):PI15-23.

A prospective double-blind, randomized clinical trial of levocarnitine to treat autism spectrum disorders.

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BACKGROUND: L-carnitine was proposed as a potential treatment for patients diagnosed with an autism spectrum disorder to improve mitochondrial dysfunction, but no prior randomized controlled trials have been conducted.

MATERIAL/ METHODS: Thirty subjects diagnosed with an ASD were randomly assigned to receive a standardized regimen (50 mg L-carnitine/kg bodyweight/day) of liquid L-carnitine (n=19) or placebo (n=11) for 3-months. Measures included changes in professionally completed Childhood Autism Rating Scale (CARS), hand muscle testing, and modified clinical global impression (CGI) forms; parent completed Autism Treatment Evaluation Checklist (ATEC), treatment adherence measurement (TAM), frequency and intensity of side effect rating (FISER)/global rating of side effect burden (GRSEB)/patient report of incidence of side effects (PRISE) forms; and lab testing.

RESULTS: Significant improvements were observed in CARS (-2.03, 95% CI=-3.7 to -0.31), CGI (-0.69, 95% CI=-1.1 to -0.06), and ATEC scores. Significant correlations between changes in serum free-carnitine levels and positive clinical changes were observed for hand muscle strength ($R^2=0.23$, $P=0.046$), cognitive scores ($R^2=0.27$, $P=0.019$), and CARS scores ($R^2=0.20$, $P=0.047$). Study subjects were protocol-compliant (average adherence was >85%) and generally well-tolerated the L-carnitine therapy given.

CONCLUSIONS: L-carnitine therapy (50 mg/kilogram-bodyweight/day) administered for 3-months significantly improved several clinical measurements of ASD severity, but subsequent studies are recommended.

PMID: 21629200