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

Geier DA, Kern JK, Davis G, King PG, Adams JB, Young JL, Geier MR.

The Institute of Chronic Illnesses, Inc., Silver Spring, MD, U.S.A. and CoMeD, Inc., Silver Spring, MD, U.S.A.

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 (R²=0.23, P=0.046), cognitive scores (R²=0.27, P=0.019), and CARS scores (R²=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.

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