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BACKGROUND: Ulcerative colitis (UC) is characterised by impaired fatty-acid oxidation; L-carnitine has a key role in fatty-acid metabolism and short-chain fatty acids such as butyrate and propionate are important energy source for intestinal epithelial cells.

AIM: To evaluate efficacy and safety of colon-release propionyl-L-carnitine (PLC) in patients with mild-to-moderate UC receiving stable oral aminosalicylate or thiopurine therapy.

METHODS: In a multicentre, phase II, double-blind, parallel-group trial, patients were randomised to receive PLC 1 g/day, PLC 2 g/day or placebo. Main inclusion criteria were as follows: age 18-75; disease activity index (DAI) score 3-10 inclusive, be under oral stable treatment with aminosalicylate or thiopurine. The primary endpoint was clinical/endoscopic response, defined as a decrease in DAI score ≥ 3 points or remission, defined as a DAI score ≤ 2 with no individual sub-score > 1.

RESULTS: Of 121 patients who were randomised, 57 of 79 (72%) patients receiving PLC (combined 1 g and 2 g cohort) had a clinical/endoscopic response vs. 20 of 40 (50%) receiving placebo (P = 0.02). Specifically, in PLC 1 g/day group, 30 of 40 (75%) patients had clinical/endoscopic response (P = 0.02 vs. placebo) and 27 of 39 (69%) in the PLC 2 g/day group (P = 0.08 vs. placebo). Rates of remission were 22/40 (55%), 19/39 (49%), 14/40 (35%) in the PLC 1 g, PLC 2 g, and placebo groups, respectively. PLC had a similar safety profile to placebo; the most common adverse events were gastrointestinal.

CONCLUSION: Propionyl-L-carnitine 1 g/day should be investigated further as a co-treatment for mild-to-moderate ulcerative colitis (NCT-01026857).

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