2011. L-Carnitine

RCT/L-Carnitine / UC/ Induction

Randomised clinical trial: the efficacy and safety of propionyl-L-carnitine therapy in patients with ulcerative colitis receiving stable oral treatment

Multicentre, pase II, double-blind, parallel-group trial.
Patients with UC with disease activity index >2-<11 under stable doce of 5ASA or thiopurine were randomized to propionyl-L-carnitine (PLC) 1g/day, 2 g/day for 4 weeks or placebo.

Primary endpoint: Clinical/endoscopic response defined as a decrease in DAI of >or equal 3 points or remission DAI <3a

Results: N=121

- Clinical response 72% PLC (combined 1 and 2 g) vs 50% placebo, p=0.02.
- Clinical/endoscopic response PLC1 75% vs PLC2 69% vs 50% placebo.
- Rates of remission 55% PLC1, 49% PLC2 and 35% placebo.
- No differences in safety profile were found with placebo

Conclusion:
Propionyl-L-carnitine 1 g / day should be investigated further as a co-treatment for mild-to-moderate ulcerative colitis

Table 2 | Clinical/endoscopic response and remission findings (ITT population, *n* = 119)*

Patient group	Placebo *n/N* (%) (1)	Combined PLC cohort *n/N* (%) (2)	PLC 1 g/day *n/N* (%) (3)	PLC 2 g/day *n/N* (%) (4)	Difference (95% CI)† Based on (2)-(1), (3)-(1) and (4)-(1)	*P* value†
Clinical/endoscopic responses						
All (*n* = 119)	20/40 (50)	57/79 (72)			22 (4-41)	0.02
			30/40 (75)		25 (5-46)	0.02
				27/39 (69)	19 (−2-41)	0.08
Mild disease (*n* = 96)‡	15/32 (47)	46/64 (72)			25 (5-46)	0.02
			24/32 (75)		28 (5-51)	0.02
				22/32 (69)	22 (−2-45)	0.08
Moderate disease (*n* = 23)‡	5/8 (63)	11/15 (73)			11 (−39-61)	0.59
			6/8 (75)		13 (−33-58)	0.59
				5/7 (71)	9 (−38-56)	0.71
Clinical/endoscopic remissions						
All (*n* = 119)	14/40 (35)	41/79 (52)			17 (−2-35)	0.08
			22/40 (55)		20 (−13-41)	0.06
				19/39 (49)	14 (−8-35)	0.23
Mild disease (*n* = 96)‡	13/32 (41)	36/64 (56)			16 (−13-37)	0.15
			21/32 (66)		25 (1-49)	0.05
				15/32 (47)	6 (−18-31)	0.61
Moderate disease (*n* = 23)‡	1/8 (13)	5/15 (33)			21 (−12-54)	0.28
			1/8 (13)		0 (−32-32)	1.00
				4/7 (57)	44 (1-88)	0.07

CI, confidence interval; DAI, disease activity index; LOCF, last observation carried forward; PLC, propionyl-L-carnitine.

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