

Impact of oral butyrate on clinical and biochemical parameters in IBD: A randomized placebo-controlled study targeting gut microbiota

Single center, double-blind, randomized placebo-controlled trial. Patients with symptomatic IBD were randomized to Butyrate-Lsc-Microencapsulated (BLM) 1,200 mg/day of microencapsulated sodium butyrate, corresponding to 600 mg of active compound) or placebo (starch capsules) supplementation plus conventional therapy.

Primary endpoint: Changes in microbiome composition (diversity, enterotypes, abundance, F/B ratio).

Results: N=140 (n=60 CD; n=80 UC)

- Two principal enterotypes defined by F/B ratio were identified. BLM exerted a bigger effect on Enterotype 1 (low F/B ratio).
- No significant changes were found in the BLM group vs placebo in the F/B ratio.
- After supplementation, clinical disease activity (p=0.013) and FC (p=0.047) improved in CD but not in UC.

Conclusion:

Supplementation with BLM, by modulating the gut microbiota, significantly improved disease outcomes and QoL in patients with IBD.

Table 2

Mann-Whitney tests between F/B ratio absolute changes between T0 and T1. **A.** Comparison between BLM and PBO groups considering the entire cohort. **B.** Comparison between BLM and PBO groups separately by IBD pathologies. **C.** Comparison between BLM and PBO groups separately by IBD pathologies and enterotypes.

A. F/B ratio absolute change (whole cohort)

IBD

BLM, N = 69 ¹	PBO, N = 70 ¹	p-value ²
0.39 (0.21, 0.75)	0.34 (0.15, 0.75)	0.2

¹ Median (IQR) ² Mann-Whitney test

B. F/B ratio absolute change by pathology

CD

CD			UC		
BLM, N = 31 ¹	PBO, N = 28 ¹	p-value ²	BLM, N = 38 ¹	PBO, N = 42 ¹	p-value ²
0.42 (0.31, 0.71)	0.26 (0.11, 0.48)	0.020	0.38 (0.13, 0.78)	0.41 (0.23, 0.92)	0.7

¹ Median (IQR) ² Mann-Whitney test

