

Lyophilised oral faecal microbiota transplantation for ulcerative Colitis (LOTUS): a randomised, double-blind, placebo-controlled trial

Double-blind, randomised, placebo-controlled trial in 2 Australian centers.

Adult patients with active ulcerative colitis after 2 weeks of amoxicillin, metronidazole and doxycycline were randomised to lyophilised FMT or placebo capsules for 8 weeks. At week 8 FMT responders were randomly assigned to either continue or withdraw FMT for a further 48 weeks.

Primary endpoints: Corticosteroid-free remission with endoscopic remission or response (total Mayo score ≤ 2 , all subscores ≤ 1) week 8

Results: N=35 (recruitment terminated earlier due to COVID)

- At week 8 CS-free remission+endoscopic remission/response occurred in 53% FMT vs 15% placebo, $p=0.027$.
- Adverse events within the 8 weeks 67% FMT vs 85% placebo and were generally mild.
- Of the FMT patients who achieved clinical or endoscopic response $n=4$ were randomized to open-label FMT or withdraw therapy $n=6$. All patients who continued FMT were in clinical, endoscopic and histologic remission at week 56 100% vs 0% of the FMT withdrawn.

Conclusion:

Antibiotics followed by orally administered FMT was associated with induction of remission in active UC. Continuing FMT was well tolerated and appeared to demonstrate clinical, endoscopic and histologic efficacy.

