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Summary

FAECALIBACTERIUM PRAUSNITZII EXL01 FOR PREVENTION OF RECURRENT CLOSTRIDIOIDES DIFFICILE INFECTION: A PHASE I CLINICAL TRIAL AND COMPARISON WITH FMT-TREATED PATIENTS

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EXL01, a single strain of Faecalibacterium prausnitzii, showed a favorable safety profile and promising efficacy in a phase I trial for multiple-recurrent Clostridioides difficile infection, with CDI recurrence in only 1 of 6 patients (16.7%).

KEY POINTS

- In a multicenter, open-label phase I trial (2024–2025), six adults with ≥3 CDI episodes within 6 months received oral EXL01 for 8 weeks following ≥10 days of vancomycin, with 8 weeks of follow-up.
- No treatment-related serious adverse events occurred; 14 non-severe adverse events were reported, with six possibly related to EXL01 (diarrhea, abdominal pain, pyrosis), all mild to moderate, self-limited, and not requiring treatment interruption.
- CDI recurrence occurred in 1/6 patients (16.7%), comparable to the mean efficacy of 81.1% (SD 8.4) observed after FMT in a matched cohort from the French Fecal Transplant Group network.
- Multi-omics analyses showed EXL01 engraftment was associated with restoration of bile acid metabolism and short-chain fatty acid production despite limited taxonomic recovery, with functional shifts consistent with those observed after FMT.
- EXL01 was detectable in stool up to 8 weeks post-treatment, and a phase II randomized study is ongoing.

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