

LMN-201 for Prevention of C. Difficile Infection Recurrence

NCT05330182

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Lumen Bioscience, Inc.
Enrollment	375 participants

Key Eligibility Criteria

Inclusion (10)

- Male or female, aged 18 or older.
- Diagnosis of CDI defined as a new or recent history of 3 or more bowel movements per day with a loose or watery consistency (Bristol Stool Scale 5, 6, or 7); a positive stool C. difficile toxin B immunoassay (stool collected no more than 7 days before first dose of LMN-201/placebo), and no other likely explanation for diarrhea. NOTE: Diarrhea is not required to be present on the day of enrollment.
- Provision of signed and dated informed consent form.
- Scheduled to receive or planning to receive a d28-day course of SOC antibiotic therapy for CDI. Participant must have been diagnosed with CDI for 7 or fewer days at time of initial study drug administration. SOC antibiotic therapy is defined as the receipt of oral fidaxomicin or oral metronidazole or oral vancomycin (see Section 8.2.6)
- May be on systemic antibiotics for an infection unrelated to the gastrointestinal tract.

... and 5 more (see full listing online)

Exclusion (23)

- Fulminant C. difficile colitis.
- Admitted or expect to be admitted to an intensive care unit.
- Underlying gastrointestinal disorder characterized by diarrhea including but not limited to chronic ulcerative colitis, Crohn's disease, celiac sprue, short bowel syndrome, dumping syndrome following gastrectomy, pancreatic insufficiency, enteric parasitic infection, viral enteritis, bacterial enteritis (salmonella, shigella, ETEC, etc.).
- Neutropenia (absolute neutrophil count of < 1000 per microliter for any reason).
- Current or previous treatment in past 3 months with any therapy likely to influence the outcome of this study, including but not limited to the following:

... and 18 more (see full listing online)

Locations (16 total)

Kaiser Permanente, Escondido, California, United States
Bridgeport Hospital, Bridgeport, Connecticut, United States
Gastroenterology Center of Connecticut, Hamden, Connecticut, United States
... and 13 more locations

<https://clinicaltrials.gov/study/NCT05330182>

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