

C. Difficile Toxin Levels in Stool From Healthy Individuals Following Standard of Care Antibiotic Treatment for CDI.

NCT07250724

Status RECRUITING
Sponsor Bactolife A/S
Enrollment 60 participants

Key Eligibility Criteria

Inclusion (5)

- Able to provide signed and dated informed consent
- Males and females between 18 - 75 years old inclusive
- Documented history of first recurrent *Clostridioides difficile* (former *Clostridium difficile*) infection (rCDI), confirmed by a positive *C. difficile* test (Toxin A+B positive or Toxin B only), with initial infection occurring within the previous 12-months.
- Must, in accordance with standard of care practices, have completed a SOC oral antibiotic therapy for the first rCDI no more than 5 days prior to the date of enrolment (baseline visit- Day 0).
- Must not have any CDI-related symptoms when enrolled in the study at baseline (Day 0).

Exclusion (13)

- Current episode of CDI or delayed symptom resolution from previous recurrence, according to the physical exam and investigator assessment
- Toxin A positive, and Toxin B negative *C. difficile* test.
- Planned CDI recurrence treatment for the duration of the study e.g., fecal microbiome transplant, probiotics, Live Biotherapeutic Products (LBPs)
- Those who are on further antibiotic treatment following initial rCDI antibiotic therapy completion.
- Pregnant or lactating women or women who intend to become pregnant within the next 3 months.

... and 8 more (see full listing online)

Locations (1 total)

Emory University Hospital, Atlanta, Georgia, United States