

# Fecal Microbiota Transplantation in Clostridioides Difficile Infection First Episode and First Recurrence

NCT05266807

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Status	RECRUITING
Phase	Phase 3
Sponsor	Benoit Guery
Enrollment	220 participants

## Key Eligibility Criteria

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### Inclusion (16)

- Adults (≥18 years old) at the time of informed consent
  - Informed consent signature
  - Medical record documentation of CDI defined as:
    - a. A first CDI episode associated with risks factors for recurrence, defined as: i. No CDI episode within the last 8 weeks ii. Current combination of CDI signs and symptoms, confirmed by medical record documentation of microbiological evidence of *C. difficile* toxin and *C. difficile* in stools shown by a CDI PCR positive test with Ct < 25 or a toxin A/B EIA positive test and without reasonable evidence of another cause of diarrhea, iii. Presenting at least one of the following risks factors for CDI recurrence:
      - age >65 years-old,
- ... and 11 more (see full listing online)

### Exclusion (19)

- Severe-complicated CDI if at least one of the following signs or symptoms are:
    - ongoing at time of screening and related to CDI: hypotension, septic shock, elevated serum lactate, ileus,
    - or were present at any time of the CDI episode and related to CDI: toxic megacolon, bowel perforation, or any fulminant course of disease (i.e. rapid deterioration of the patient).
  - Prior FMT within 6 months of randomization,
  - Prior colectomy, colostomy, ileostomy, or gastrectomy
- ... and 14 more (see full listing online)

## Locations (7 total)

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Universitätsspital, Basel, Basel, Switzerland  
Inselspital Bern, Bern, Canton of Bern, Switzerland  
HFR Fribourg - Hôpital cantonal, Fribourg, Canton of Fribourg, Switzerland  
... and 4 more locations