

Evaluation of EXL01, a New Live Biotherapeutic Product to Prevent Recurrence of Clostridioides Difficile Infection in High-risk Patients

NCT06306014

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| Status | RECRUITING |
| Phase | Phase 1, Phase 2 |
| Sponsor | Hospices Civils de Lyon |
| Enrollment | 56 participants |

Key Eligibility Criteria

Inclusion (10)

- Adult patient ≥18 years of age
 - ≥1 episode of proven C. difficile infection (≥3 liquid stools per day and detection of toxigenic C. difficile in stool by PCR or enzyme-linked immunosorbent assay or immunochromatography or toxigenic culture) within 6 months with an interval ≥12 weeks since the end of treatment of the previous episode of resolved CDI or 2nd episode of proven C. difficile infection (≥3 liquid stools per day and detection of toxigenic C. difficile in the stools by PCR or enzyme-linked immunosorbent assay or immunochromatography or toxigenic culture) within 6 months with an interval ≥12 weeks since the end of treatment of the previous episode of resolved CDI with at least one of the following risk factors:
 - Age ≥70 years
 - Chronic renal failure (haemodialysis or GFR <60ml/min)
 - History of severe or severe-complicated CDI (excluding current episode) according to ESCMID 2021 criteria
- ... and 5 more (see full listing online)

Exclusion (33)

- Currently participating or has participated in a study with an investigational compound or device within 3 months prior to the first dose of the study intervention.
 - Severe C. difficile infection severe (defined by the presence of a white blood cell count >15×10⁹ cells/L or a body temperature >38.5°C or >50% increase in the patient's baseline creatinine related to CDI at the time of V1) and/or complicated (defined by any of the factors attributed to current Clostridioides difficile infection (CDI): hypotension, septic shock, elevated serum lactate, ileus, toxic megacolon, intestinal perforation or any fulminant course of the disease)
 - Refractory C. difficile infection defined as lack of response to well-conducted per os vancomycin or fidaxomicin treatment with ≥3 liquid stools per day after ≥5 days of treatment
 - Cirrhosis with Child C score
 - Hospitalization in continuing care unit or intensive care unit
- ... and 28 more (see full listing online)

Locations (9 total)

CH Annecy Genevois Service de Maladies infectieuses, Annecy, France
Service d'hépatogastroentérologie - CHU Estaing, Clermont-Ferrand, France
CHU Grenoble Service Maladies infectieuses et tropicales, Grenoble, France
... and 6 more locations

<https://clinicaltrials.gov/study/NCT06306014>

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