

Advantages and Disadvantages of TOXCLEAN As Add on Treatment to SOC in Patients with Clostridium Difficile-associated Diarrhea

NCT06839209

Status	RECRUITING
Phase	Not Applicable
Sponsor	ABResearch S.r.l.
Enrollment	18 participants

Key Eligibility Criteria

Inclusion (5)

- Age e 18 years, male or female, at the time of informed consent
- Signed informed consent by patient, or where applicable, patient's legally authorized representative;
- Diagnosis of recurrent CDAD, defined as those episodes of C. Difficile associated diarrhea occurring 2-8 weeks after either the symptoms resolution of a previous CDAD episode or C. difficile negativization of fecal sample.
- Detection of C. difficile toxins by nucleic acid amplification tests (NAAT), EIA or GDH;
- Received at least one course of adequate antibiotic therapy for CDAD (e 10 days of vancomycin at a dose of e125 mg four times per day, e 10 days of metronidazole at a dose of 500mg three times per day or fidaxomixin 200mg twice a day for 10 days)

Exclusion (6)

- History of C. difficile complicating inflammatory bowel disease (Crohn's disease, ulcerative colitis), or history of bowel resection surgery (other than uncomplicated appendectomy) or history of other infectious diarrhea or diarrhea of unknown etiology since the initial episode of CDAD;
- Participants who require oral anticoagulant medications, including but not limited to warfarin and NOACs (novel oral anticoagulants);
- Major gastrointestinal surgery within 3 months of enrollment;
- History of swallowing difficulties, including dysphagia or odynophagia for liquids or solids;
- Clinically immunocompromised due to any primary immune or autoimmune deficiency, as a result of chronic disease, cancer or medication used to treat these diseases

... and 1 more (see full listing online)

Locations (1 total)

Policlinico Gemelli, Roma, Italy