Secondary Prevention of Clostridioides Difficile Using Vancomycin

NCT06979609

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	McGill University Health Centre/Research Institute of the McGill University Health Centre
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (4)

- Inpatient or outpatient adults (e18 years old) treated at the participating institutions.
- An episode of CDI within the preceding 120 days (rationale in 2.4), diagnosed by both a positive C. difficile assay (including PCR toxin gene detection47, toxin enzyme immunoassay, and/or cell cytotoxicity neutralization assay29) and the presence of either e3 unformed stools in \<24 hours with a duration \>24 hours, endoscopic/histologic evidence of pseudomembranous colitis, or ileus29.
- Treatment of the qualifying CDI episode with vancomycin or fidaxomicin for e10 days, clinical cure (d3 unformed stool per 24 hours in e2 days10) by the conclusion of therapy, and e1 day has elapsed since cessation of CDI treatment.
- Receipt of d3 days of at least one oral or intravenous systemic antibiotic for the treatment of an intercurrent confirmed or suspected bacterial infection, for which therapy is planned for at least one additional consecutive day in duration.

Exclusion (16)

- Treatment of the qualifying episode of CDI with metronidazole monotherapy or intravenous immunoglobulins.
- Planned treatment with or treatment of the qualifying episode of CDI with fecal microbiota transplantation (FMT), bezlotoxumab, VOWST, or REBYOTA.
- Inability to take medications orally or crushed by nasogastric tube.
- Prior total colectomy.
- Severe intolerance or allergy to oral vancomycin.

... and 11 more (see full listing online)

Locations (1 total)

McGill University Health Centre, Montreal, Quebec, Canada