Prevention of Recurrent C. Difficile Infection Study With AZD5148 Monoclonal Antibody

NCT07285213

Status	RECRUITING
Phase	Phase 2
Sponsor	AstraZeneca
Enrollment	230 participants

Key Eligibility Criteria

Inclusion (6)

- Participant must be e 18 years of age at the time of signing the informed consent, capable of giving signed informed consent.
- Participants with a qualifying C. difficile infection episode at the time of providing informed consent defined by:
- Positive local C. difficile toxin test (eg, immune assay or CCNA) on an unformed stool sample collected during this episode, and
- Receipt of standard of care antibacterial drug therapy for C. difficile infection (fidaxomicin, vancomycin or metronidazole) for this episode, with planned duration of at least 10 and at most 25 days at time of IMP administration.
- Note: Diarrhea is not required to be present on the day of investigational medicinal product (IMP) administration.

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

Exclusion (9)

- History of inflammatory bowel disease (eg, ulcerative colitis, Crohn's disease, microscopic colitis).
- Participant with a non - CDI (C. difficile infection) condition such that the participant routinely passes loose stool (eg, patients with an ostomy)
- Planned surgery for C. difficile infection within 24 hours of enrollment
- Current toxic megacolon and/or small bowel ileus
- Any history of total colectomy or bariatric surgery (bariatric surgery which does not disrupt the gastrointestinal lumen, ie, restrictive procedures such as banding, are permitted).

... and 4 more (see full listing online)

Locations (111 total)

Research Site, Phoenix, Arizona, United States
Research Site, Chula Vista, California, United States
Research Site, Sacramento, California, United States
... and 108 more locations