

Washed Microbiota Transplantation for Clostridioides Difficile Infection

NCT06106698

Status	RECRUITING
Sponsor	The Second Hospital of Nanjing Medical University
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (5)

- At the time of informed consent, male or non-pregnant or non-lactating female.
- The diagnostic criteria for *C. difficile* infection are met during screening:
- Medical records confirming CDI prior to screening (laboratory tests are positive for *Clostridium difficile* or its toxin): *Clostridium difficile* toxin test is positive (determined by Elisa test), or colonoscopy indicates pseudomembranous enteritis; Or Glutamate dehydrogenase positive, toxin negative, there are obvious causes and diarrhea.
- CDI-related diarrhea episodes, i.e., defecation e3 times/day for at least two consecutive days with unformed stools (Bristol score 6-7).
- The subject or his/her legal representative gives informed consent, fully understands the purpose of the study, is able to communicate effectively with the investigator, and comprehends and complies with the requirements set forth in the study.

Exclusion (6)

- Subjects with immune deficiencies (such as HIV infection, or neutrophils $<0.5 \times 10^9/L$ in absolute value, or lymphocytes $<0.5 \times 10^9/L$, etc.), or on immunosuppressants, or on medium to high doses of steroid hormones (e20g/d of prednisone or equal doses of steroid hormones).
- There is rectal outlet obstruction (such as rectal mucosal prolapse) or significant intestinal stenosis assessed by the investigator and colonic transendoscopic enteral tubing cannot be performed.
- Confirmed or clinically suspected infection with pathogenic microorganisms other than *Clostridium difficile* prior to screening.
- Have had major abdominal surgery (other than laparoscopic gallbladder or appendectomy), previous partial or total colectomy, previous partial small intestinal resection, or previous gastroduodenal surgery within 6 months prior to screening.
- At the time of screening, the subject or his/her legal representative refuses to take effective contraception within 3 months after the last treatment.

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

Locations (1 total)

The second affiliated hospital of Nanjing Medical University, Nanjing, Jiangsu, China