

## A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 STUDY OF VE303 FOR PREVENTION OF RECURRENT CLOSTRIDIODES DIFFICILE INFECTION: THE RESTORATIVE303 STUDY

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** Not specified

This study is NOT accepting healthy volunteers

#### Inclusion Criteria:

- at least 12 years old - laboratory-confirmed Clostridium Difficile Infection (CDI) and at least one prior occurrence of CDI within the last 6 months - OR 75 years or older with laboratory confirmed CDI - OR CDI with additional risk factors - see link to [clinicaltrials.gov](http://clinicaltrials.gov) for additional inclusion and exclusion criteria

#### Exclusion Criteria:

- history of chronic diarrhea unrelated to CDI - history of celiac disease, inflammatory bowel disease, microscopic colitis, short gut, GI tract fistulas, or a recent episode (within 6 months) of intestinal ischemia or ischemic colitis

### Conditions & Interventions

#### Conditions:

Rare Diseases, Infectious Diseases

#### Keywords:

C. Diff Infection, CDI, Clostridium Difficile, Clostridium Difficile Infections, Diarrhea

### More Information

**Description:** The purpose of RESTORATIVE303 is to see if the study drug, which is called VE303, is safe and effective in preventing another episode of Clostridioides Difficile Infection (CDI). VE303 is an investigational drug that has 8 strains of live bacteria, called "commensals." Commensals are the type of bacteria that live in harmony with the body, without harming health. These specific bacteria are often found in the intestines of normal, healthy people. They were selected for inclusion in VE303 because they rarely infect humans (mostly in very weakened patients), they do not carry any toxins that can make one sick, and they are not known to carry any risk of creating or spreading resistance to antibiotics.

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**Phase:** PHASE3

**IRB**

**Number:** STUDY00022419

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