

# Microbiome therapeutic beats placebo for recurrent *C. difficile*

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(HealthDay)—An investigational microbiome therapeutic composed of

purified Firmicutes spores, SER-109, is superior to placebo for treatment of recurrent *Clostridioides difficile* infection, according to a study published in the Jan. 20 issue of the *New England Journal of Medicine*.

Paul Feuerstadt, M.D., from the Yale University School of Medicine in New Haven, Connecticut, and colleagues conducted a phase 3, double-blind, randomized trial involving patients who had three or more episodes of *C. difficile* infection. One hundred eighty-two patients were enrolled and randomly assigned to either SER-109 or placebo after standard-of-care antibiotics.

The researchers found that 12 and 40 percent of patients had recurrence of *C. difficile* infection in the SER-109 and placebo groups, respectively (relative [risk](#), 0.32) at up to eight weeks of follow-up. In analyses stratified according to age stratum, SER-109 led to less frequent recurrence than [placebo](#) (relative risks, 0.24 and 0.36 for those younger than 65 years of age and 65 years and older, respectively); results were similar in analyses stratified according to antibiotic received (relative risks, 0.41 and 0.09 for vancomycin and fidaxomicin, respectively). The number of adverse events, which were mostly mild-to-moderate and gastrointestinal in nature, was similar in the two groups. As early as week 1, SER-109 dose species were detected; they were associated with bile-acid profiles known to inhibit *C. difficile* spore germination.

"The lower incidence of recurrence achieved with SER-109 administered after treatment with standard-of-care antibiotics represents a 68 percent [lower risk](#) than that with [antibiotics](#) alone and a number needed to treat of 3.6 to avoid one recurrence of *C. difficile* [infection](#)," the authors write.

The study was funded by Seres Therapeutics, the developer of SER-109.

**More information:** [Abstract/Full Text \(subscription or payment may be required\)](#)

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