

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 <u>risk</u>, 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 <u>placebo</u> (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 <u>lower risk</u> than that with <u>antibiotics</u> alone and a number needed to treat of 3.6 to avoid one recurrence of C. difficile <u>infection</u>," the authors write.

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



More information: <u>Abstract/Full Text (subscription or payment may be required)</u>

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