

# NIH launches Phase I clinical trial of novel drug to treat *Clostridium difficile* infection

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This illustration depicts a single Gram-positive *C. difficile* bacillus. Credit: CDC

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has launched an early-stage clinical trial of CRS3123, an investigational oral antibiotic intended to treat *Clostridium difficile* (*C. difficile*) infection. CRS3123 (previously known as REP3123) is a narrow-spectrum agent that inhibits *C. difficile* growth while sparing normal intestinal bacteria.

The Phase I trial will enroll up to 30 healthy men and women ages 18 to 45 in a dose-escalation study to evaluate the investigational drug's safety and tolerability. Quintiles, through Dynport Vaccine

Company, is conducting the study of CRS3123. The medication is being provided by its developer, Crestone, Inc., a pharmaceutical company based in Boulder, Colo.

*C. difficile* infection affects the digestive track with manifestations ranging from mild diarrhea to life-threatening colitis. Infection most commonly affects patients in hospitals or long-term care facilities and people who have taken antibiotics. Each year, roughly 250,000 people in the United States require hospital care for *C. difficile* infection and at least 14,000 people die from the infection, according to the U.S. Centers for Disease Control and Prevention (CDC). As a result, the CDC identified *C. difficile* as an urgent public health threat in its 2013 report on antibiotic resistance. Resistance to the antibiotics currently used to treat *C. difficile* is not yet a problem, but the bacteria spreads rapidly because it is naturally resistant to many drugs used to treat other infections. Recurrent infections pose a particular clinical challenge, especially those caused by a newer, stronger *C. difficile* strain, which result in up to 25 percent of patients needing additional therapy.

In the new clinical trial, [participants](#) will be randomly assigned into three groups of 10 participants each (8 participants will receive the investigational drug; 2 participants will receive a placebo pill). In the first group, participants will receive either 200 milligrams (mg) of CRS3123 or placebo twice daily for 10 days. Based on the review of safety data from this group, the study will progress to a second and then a third group of volunteers with a maximum possible dose of 600 mg twice daily. Participation in the trial will require an inpatient stay of 12 days to allow for monitored dosing and physical evaluations, including blood tests and urinalysis. Participants will be evaluated on an outpatient basis 18 and 29 days after receiving the first dose of the [investigational drug](#). The study is expected to be completed by March 2015.

Provided by NIH/National Institute of Allergy and  
Infectious Diseases

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