

First new *C. difficile* drug in a generation superior to existing treatments: Researchers

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Clostridium difficile infection (CDI) is a significant and growing problem in hospitals and other health care facilities, but no new drugs to treat the condition have been developed in several decades. However, a large-scale, phase 3 trial conducted by Canadian and U.S. researchers shows that the new antibiotic Fidaxomicin is superior to existing treatments, demonstrating a 45 percent reduction in recurrences vs. the existing licensed treatment. Their results were published in February, 2011 in *The New England Journal of Medicine*.

"There wasn't much interest in *C. difficile* for many years, because it wasn't considered a serious disease," said study co-author Dr. Mark A. Miller, head of the Division of [Infectious Diseases](#) and Chief of Microbiology at the Jewish General Hospital in Montreal, and a clinical investigator at the Lady Davis Institute for Medical Research. "However, over the past decade the bacterium has mutated into something much more serious that has caused epidemics worldwide. It is particularly notorious for recurrences. About 20 to 30 percent of patients suffer relapses. Recurrent *C. difficile* is very difficult to treat, and this has spurred interest in newer and better treatments."

Fidaxomicin, developed by Optimer Pharmaceuticals of San Diego, is the first in a new class of narrow-spectrum macrocyclic antibiotics. It is only minimally absorbed from the gut into the bloodstream and is specifically targeted at *C. difficile* in the intestine. Thus the drug acts by killing *C. difficile* bacteria without affecting the beneficial flora in the human gut which help stave off recurrences.

A total of 629 patients were enrolled in the multicentre, double-blind, randomized, parallel-group trial conducted between May 9, 2006, and August 21, 2008. They received Fidaxomicin (200 mg twice daily) or the antibiotic vancomycin (125 mg four times daily) orally for 10 days. Vancomycin was first developed in the 1950s, and to date is the only FDA- and Health Canada-approved treatment for CDI.

"These results showed that recurrence of CDI is significantly less likely to occur following treatment with Fidaxomicin versus [vancomycin](#)," said lead author, Thomas J. Louie, M.D., Medical Director, Infection Prevention and Control for the Calgary Health Region and professor in the Departments of Medicine and Microbiology-Infectious Diseases, University of Calgary.

"Anybody who knows *C. difficile* recognizes that recurrences are the major problem with this disease," agreed Dr. Miller, also assistant professor in Medicine, Microbiology and Immunology at McGill University. "Anything that can reduce the recurrence rate, especially as dramatically as Fidaxomicin, is a very important milestone in the treatment of *C. difficile*."

Provided by Jewish General Hospital

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