

Groundbreaking clinical trial looks at fecal transplant as treatment for *C. difficile*

21 August 2012

For patients with *Clostridium difficile* (*C. difficile*), a persistent and potentially deadly bacterial illness, severe diarrhea, abdominal pain, nausea and vomiting are an everyday event. This particularly virulent infection is prone to recurrence, even after multiple courses of expensive antibiotics, and treatment options are limited for patients who continually relapse or develop antibiotic resistance.

Now, a new National Institutes of Health research grant awarded to Colleen Kelly, M.D., a [gastroenterologist](#) with the Center for Women's Gastrointestinal Medicine at the Women's Medicine Collaborative, and co-investigator Lawrence Brandt, M.D., from the Albert Einstein School of Medicine in New York, will test whether an unconventional yet promising treatment known as fecal bacteriotherapy, or fecal transplantation, is an [effective therapy](#) for [patients](#) with relapsing *C. difficile*.

While it sounds unpleasant, previous research suggests fecal transplantation, which involves transplanting healthy donor stool into the patient's colon during a colonoscopy, is extremely successful; according to published case studies, the procedure has "cured" relapsing *C. difficile* in 89 percent of patients without any complications. However, few physicians know about the procedure, which has been around for more than 50 years, and to date there have been no published prospective clinical trials of fecal transplant for *C. difficile*.

Kelly's research will be the first randomized controlled clinical trial of this procedure as a treatment for relapsing *C. difficile*.

"Our goal is to clearly demonstrate to both the medical community and health insurers that fecal transplant is an viable, safe, inexpensive, and ultimately [curative treatment](#) for patients with relapsing *C. difficile*," said Kelly. "We hope this

research is the first step toward developing standard treatment protocols for this procedure and making it more widely available to the many patients who are suffering from recurring *C. difficile*."

C. difficile affects tens of thousands of Americans each year, particularly patients in hospitals or long-term care facilities, and typically occurs after a dose of antibiotic medications. It has been increasing in both incidence and severity over the last decade, including otherwise healthy people who aren't hospitalized or taking antibiotics. It causes 14,000 deaths annually, according to the Centers for Disease Control and Prevention.

C. difficile disrupts the balance of the normal, healthy, protective bacterial flora found in the colon. When that happens - often following a dose of antibiotics - invasive bacteria like *C. difficile* can grow, proliferate and produce toxins that make patients sick.

Approximately 20 percent of patients have recurring *C. difficile* that does not respond to antibiotics. Patients who experience one recurrence have a 40 percent risk of further relapse, while those with two or more episodes face a 60 percent relapse risk. While the first relapse is generally treated with a second course of antibiotics, current guidelines recommend a tapering course of an expensive antibiotic known as oral vancomycin following a second recurrence.

During a fecal transplant, healthy donor stool is mixed with saline and infused into the colon during a standard outpatient [colonoscopy](#) procedure. The patient identifies the donor - usually a family member or close friend - ahead of time, and the donor undergoes a rigorous screening process. A stool sample is obtained the morning of the procedure.

Kelly, who is also a clinical assistant professor of medicine at The Warren Alpert Medical School of

Brown University, says fecal transplant works because the donor stool contains the healthy bacteria needed to restore and repopulate the patient's colon with what she calls an "army of good bacteria" to keep *C. difficile* from overgrowing and causing disease.

Kelly and Brandt hope to enroll 48 patients in this randomized study, which will determine if fecal transplantation, using stool from a healthy volunteer donor, provides a cure for relapsing *C. difficile* infection. Collaborating investigators at the University of Minnesota will analyze the complex bacterial communities in stool collected from patients both before and after transplant, as well as their donors.

"Given the increasing incidence and severity of *C. difficile* infection, the problem of recurrent disease in a significant number of patients, and the economic burden and drug-resistant infections associated with long term use of oral antibiotics, we need this clinical trial to determine whether fecal transplant is an effective treatment for relapsing infection," said Kelly.

Provided by Lifespan

APA citation: Groundbreaking clinical trial looks at fecal transplant as treatment for *C. difficile* (2012, August 21) retrieved 23 April 2021 from <https://medicalxpress.com/news/2012-08-groundbreaking-clinical-trial-fecal-transplant.html>

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