

Clinical trials focus on new treatments for Crohn's Disease, dangerous bacterium

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Several clinical trials at the University of Cincinnati (UC) are focused on potential treatments for two serious gastroenterological illnesses—Crohn's disease and *Clostridium difficile*, or *C. difficile*.

Bruce Yacyshyn, MD, professor of medicine in the division of digestive diseases and principal investigator for the Cincinnati sites on both multicenter, international trials, says researchers are working with the pharmaceutical companies Janssen and Merck to find new therapies for a potentially life-altering autoimmune disease and for a condition, once only common in the autoimmune-compromised hospital population, that is now becoming an epidemic within the general population.

Yacyshyn says the first study—called UNITI-1—will examine how a Food and Drug Administration (FDA)-approved drug used for psoriasis may help in treating patients with Crohn's disease who experience treatment failure with the other drugs commonly prescribed.

Crohn's disease is an inflammatory bowel disease that occurs when the immune system attacks the gastrointestinal tract. Crohn's can affect any part of the tract and inflame all layers of the intestinal wall; it most typically begins in younger years, with an average age of trouble occurring at 36.

Besides experiencing abdominal pain, bloody stools, diarrhea and other serious problems, such as growth failure because of a lack of nutrients, individuals with Crohn's have an increased risk of colorectal cancer.

"There are currently three FDA-approved monoclonal biologic treatments for Crohn's disease," Yacyshyn says, explaining that these treatments are helpful because they target a pathway which activates the immune response in the body and produces the proteins that attack the gastrointestinal tract."

"This clinical trial will focus on a therapy that will target a different pathway, giving hope to patients who have not experienced success with one of the other treatments or whose treatments begin to lose effect," he adds.

The second clinical trial is looking at a single injection to see if this treatment could clear initial or recurrent onset of *C. difficile*.

C. difficile is a bacterium that can be naturally found inside the digestive tract, but if an overgrowth occurs, it can cause symptoms ranging from diarrhea to life-threatening inflammation of the colon. Illness from *C. difficile* was once more common in older adults who were hospitalized or among people in long-term care facilities, and typically occurred after use of antibiotic medications.

"In recent years, *C. diff* infections have become more frequent, more severe and more difficult to treat," says Yacyshyn, adding that treatment is expensive, ranging anywhere from \$4,000 to \$9,000. "Tens of thousands of people in the U.S. get sick from *C. diff* each year, and a rise in cases is being seen in the community—in healthy people who aren't hospitalized or taking antibiotics."

In this Phase III trial, researchers will be giving individuals who currently test positive for *C. difficile* one of two antibodies which recognize the toxins produced by the bacteria.

"The infusion will be given with concurrent, standard-of-care antibiotic

therapy. Following this one-time infusion, follow-up will occur over three months with a possible follow-up extension to nine months,” says Yacyshyn, adding that this is for patients 18 years or older. “There is currently no optimal treatment for all C. difficile-positive patients, and the antibiotics usually prescribed for it are not effective in all cases.

“Addition of this treatment alongside current standard-of-care treatment may cut down on recurrence and help clear both toxin and bacteria after initial infection.

“While different, both of these conditions affect a large number of the population and could cause major complications if not treated properly,” he adds. “The hope is that these [clinical trials](#) help in uncovering additional or more beneficial treatments for Crohn’s disease and C. difficile.”

More information: Yacyshyn receives research support from Merck but cites no other conflict of interest.

Provided by University of Cincinnati

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