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NYU School of Medicine announces new clinical trial for ulcerative colitis

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A new clinical trial designed to study how worm eggs may relieve symptoms of ulcerative colitis (UC) will begin enrolling patients at NYU School of Medicine's Clinical and Translational Science Institute. This unusual therapy has been used in previous clinical trials on patients with inflammatory bowel diseases, but the mechanism of action is unclear.

"The goal of this study is to understand the mechanisms that may explain why worm eggs can improve the symptoms of UC." says the study's Principal Investigator, P'ng Loke, PhD, assistant professor of microbiology. "Understanding these mechanisms may lead to new treatment strategies and also help identify people that are most likely to respond to treatment with worm eggs."

UC is a chronic disease that is characterized by open sores or ulcers in the lining of the colon. According to the Crohn's and Colitis Foundation of America, the disease is estimated to affect 700,000 Americans. Symptoms include abdominal pain and bloody diarrhea. While the cause is unknown, studies suggest that a defective response against commensal (normal microflora) gut bacteria could be responsible.

Colitis is common in North America and Northern Europe, where helminth (parasitic worm) infections are rare. Conversely, the disease is rare in Asia, Africa, and Latin America, where helminth infections are endemic, leading researchers to hypothesize that the worms offer protection against this inflammatory bowel disease. In animal models of autoimmunity these worms have suppressed inflammation, and clinical

trials indicate that helminth therapy can be beneficial in relieving symptoms of inflammatory bowel diseases.

In 2005, Dr. Joel Weinstock and colleagues at the University of Iowa published a series of human studies showing that eggs from the pig whipworm Trichuris suis (TSO) had positive effects in both Crohn's disease as well as ulcerative colitis patients, which are two different types of inflammatory bowel diseases. Several large studies on TSO are underway for a number of different immune disorders.

In 2010, Dr. Loke and his colleagues reported a detailed study of a man with UC who ingested Trichuris trichiura eggs to relieve his own symptoms. Based on the samples that were analyzed from this man, the researchers hypothesized that the immune response activated to expel the parasites through increased cell turnover in the intestinal lining and increased mucus production may have improved his symptoms. They followed up these observations with a study on monkeys that showed that this response also changed the type of bacteria and reduced the amount of bacteria attached to the intestinal lining.

"We think that by altering the lining of the intestine, the worms may change the quantity and type of bacteria that are attached to the intestinal wall." says Dr. Loke. "We are now ready to test this idea in a human clinical trial."

More information: This trial is actively enrolling patients. There is no fee to participants. We are seeking individuals with moderate disease, but have not yet tried biologics. For more information about this trial please go to clinicaltrials.gov/ct2/show/NCT01433471 or email helminthic.therapy@nyumc.org

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