

Two studies identify potential new drug for Crohn's disease and ulcerative colitis

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Vedolizumab, a new intravenous antibody medication, has shown positive results for treating both Crohn's disease and ulcerative colitis, according to researchers at the University of California San Diego, School of Medicine. The findings, published in two papers, will appear in the August 22 issue of the *New England Journal of Medicine (NEJM*).

William Sandborn, MD, principal investigator of the Crohn's disease study, said the results offer new hope to the more than one million Americans who suffer from <u>inflammatory bowel disease</u> (IBD) and do not respond to treatment. Both studies showed that the use of vedolizumab resulted in remission and discontinued use of prednisone, a common yet difficult to tolerate drug used to treat both diseases.

"The two trials showed highly encouraging results for patients suffering from moderate-to-severe Crohn's disease and ulcerative colitis when conventional therapy such as steroids, immune suppressive drugs and anti-<u>tumor necrosis factor</u> (TNF) biologic drugs failed," said Sandborn, of the Division of Gastroenterology at UC San Diego School of Medicine and director of the Inflammatory Bowel Disease Center at UC San Diego Health System. "This is a disease modifying drug. In many cases of patients with ulcerative colitis, complete healing of the bowel was observed and maintained with continued use of vedolizumab."

Vedolizumab is targeted to disease within the digestive tract so other areas of the body remain unaffected. It blocks <u>immune system cells</u> that release proteins called cytokines that trigger inflammation, causing tissue



damage and diarrhea to move into the <u>small intestine</u> and colon. The targeted nature of the medication helps reduce troublesome side effects such as weight gain, nausea and headaches caused by other treatment options. Current treatments such as steroids and immunosuppressive medications broadly suppress the immune system, which can also put the patient at risk for infections.

"Inflammatory bowel disease causes severe ongoing bouts of illness that adversely affect a patient's quality of life at home and work," said Sandborn. "These latest findings will potentially lead to a new drug therapy that will improve a patient's overall lifestyle."

Crohn's disease and ulcerative colitis are forms of inflammatory autoimmune diseases, impacting the small intestine and colon. Clinical symptoms include abdominal pain, diarrhea, intestinal bleeding, fecal urgency and weight loss. Serious complications such as bowel obstruction, colon cancer, malnutrition and abscesses can also occur, resulting in hospitalization and the possible surgical removal of portions of the bowel and colon.

Eight hundred and ninety five patients were part of the <u>ulcerative colitis</u> trial conducted in 34 countries, and 1,115 patients were part of the Crohn's disease clinical trial conducted in 39 countries. Eligible patients for both trials were between 18 and 80-years-old and were treated for 52 weeks in the placebo-controlled studies. Benefits could be seen six weeks into the study.

Provided by University of California - San Diego

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