

Study Finds Potential New Drug Therapy for Crohn's Disease

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Ustekinumab Induces, Sustains Clinical Response in Patients

Ustekinumab, an antibody proven to treat the skin condition psoriasis, has now shown positive results in decreasing the debilitating effects of Crohn's Disease, according to researchers at the University of California San Diego, School of Medicine. The study will appear in the October 18, 2012 issue of the *New England Journal of Medicine (NEJM)*.

Results from the clinical trial showed ustekinumab (Stelara) increased clinical response and remission in patients suffering from moderate-to-severe Crohn's Disease - a form of inflammatory bowel disease (IBD) that can lead to a variety of distressing symptoms, including diarrhea, intestinal bleeding and weight loss. Serious complications such as bowel obstruction and abscesses can also occur.

"Our biggest challenge in treating patients with Crohn's Disease is managing patients whose bodies are resistant to tumor necrosis factor (TNF) inhibitors such as Remicade, Humira and Cimzia," said Sanborn, MD, principal investigator and chief of the Division of Gastroenterology at the UC San Diego School of Medicine. "Ustekinumab blocks two proteins that cause inflammation, interleukin 12 and 23. This finding is a significant first step towards a new treatment option for these patients."

One third of patients with moderate-to-severe Crohn's Disease do not respond to current treatment with TNF inhibitors, which regulates the body's immune system and inflammation. Another one third of patients only have a temporary response.

Five hundred and twenty six patients were part of the randomized trial, which was conducted in 12 countries. Eligible patients were at least 18 years of age and had a confirmed diagnosis of Crohn's Disease for at least three months.

The patients were treated for 36 weeks in the placebo-controlled study. They were given an intravenous dose of ustekinumab at the beginning of the study and a subcutaneous dose every eight weeks. Benefits could be seen as early as six weeks of therapy.

Among patients treated, serious infection was reported in five patients and a basal-cell carcinoma, a form of skin cancer, was reported in one patient.

"These promising initial results are now being followed up and confirmed with additional Phase 3 induction trials – [UNITI-1](#) and [UNITI-2](#). A Phase 3 maintenance trial ([IM-UNITI](#)) will also be conducted in which the patients who respond to ustekinumab will receive additional treatment for one year," said Sandborn, director of the Inflammatory Bowel Disease Center at UC San Diego Health System. "Our goal is to increase clinical response and put the disease in remission to improve the patient's quality of life."

Crohn's Disease affects approximately 700,000 Americans. There is no cure for the disease, and severe flare ups can result in surgery where the large intestine is removed.

Researchers who also participated in this study include Christopher Gasink, MD, Long-Long Gao, PhD, Marion A. Blank, PhD, Jewel Johanns, PhD, Cynthia Guzzo, MD, all at Janssen Research & Development, Springhouse, PA; Bruce E. Sands, MD, and Simon Lichtiger, MD, Mount Sinai School of Medicine, New York; Stephen B. Hanauer, MD, University of Chicago; Stephan Targan, MD, Cedars Sinai Medical Center; Paul Rutgeerts, MD, PhD, University Hospital Gasthuisberg, Leuven, Belgium; Subrata Ghosh, MD, and Remo Panaccione, MD, University of Calgary; Gordon Greenberg, MD, Mount Sinai Hospital, University of Toronto; Willem J.S. de Villiers, MD, PhD, University of Kentucky Medical Center, Lexington; Stefan Schreiber, MD, Christian Albrechts

University, University Hospital, Schleswig-Holstein, Kiel, Germany; and Brian G. Feagan, MD, Robarts Research Institute, London, ON.

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The Division of Gastroenterology at UC San Diego Health System is nationally recognized for its innovative and comprehensive care of patients by a multidisciplinary team of specialists in gastroenterology, endoscopy, oncology, surgery, transplantation and radiology. [The Inflammatory Bowel Disease Center](#) is dedicated to diagnosing and treating people with IBD from around the world. The center's leadership in IBD medical research means patient access to clinical trials for the newest therapies and advanced surgical techniques for the treatment of this challenging condition.