

2-drug combo twice as effective for Crohn's disease remission

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A study led by Mayo Clinic suggests remission from Crohn's disease may be more likely if patients get biologic therapy combined with immune-suppressing drugs first instead of immune-suppressing drugs alone. The study, published in the April 15, 2010 issue of the *New England Journal of Medicine*, found treatment of moderate to severe Crohn's disease with infliximab plus azathioprine allows more patients to achieve remission and mucosal healing than therapy with azathioprine alone.

"These study results are strong enough to change clinical practice," says William Sandborn, M.D., gastroenterologist and vice chair of the Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester. "They have certainly changed mine."

The researchers in the international, multi-center SONIC (Study of Biologic and Immunomodulator Naive Patients in [Crohn's Disease](#)) study recruited 508 patients with Crohn's disease who were naive to immunomodulator drugs. The patients were then randomized to treatment: 169 [infliximab](#) monotherapy, 170 azathioprine monotherapy, or 169 infliximab plus azathioprine combination therapy. Patients underwent colonoscopies at baseline and again at week 26. Patients still in the trial at week 30 were given the option of continuing in a blinded extension trial for another 20 weeks.

Researchers found that 57 percent of patients who received combination therapy with infliximab and azathioprine achieved steroid-free remission

after 26 weeks. This is compared to 44 percent of patients who achieved remission with infliximab monotherapy and 30 percent with azathioprine alone. Both the infliximab combination therapy and infliximab monotherapy groups were statistically superior to the azathioprine group. These results were durable through week 50 and overall results show comparable safety in the three groups.

Historically, patients with Crohn's disease have been treated sequentially with steroids, then azathioprine, then monoclonal antibodies such as infliximab. The study definitively demonstrates that infliximab-based strategies are more effective than azathioprine, explains Dr. Sandborn.

"Results of this study will provide doctors and their patients with more information on how to use these drugs most appropriately to most effectively treat Crohn's disease," says Dr. Sandborn. "For the first time, we have longer term outcome data on the advantages of [combination therapy](#) that will help guide our treatment of patients with Crohn's disease."

Crohn's disease is an inflammatory disorder of the gastrointestinal tract that affects an estimated 500,000 people in the United States. Symptoms include abdominal pain, fever, nausea, vomiting, weight loss and diarrhea. Crohn's disease has no known medical cure. One common therapy used to manage the disease is a series of intravenous infusions of infliximab, which blocks tumor necrosis factor, an important cause of inflammation in Crohn's disease. Azathioprine is an orally administered, small molecule immunosuppressive which has a broad immunosuppressive effect.

Each year, physicians at Mayo Clinic's campuses in Arizona, Florida and Minnesota treat approximately 2,000 patients who have Crohn's disease. For more information on the treatment of Crohn's disease at Mayo Clinic click this link: <http://www.mayoclinic.org/crohns/>.

Provided by Mayo Clinic

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