

## Treatment of Crohn Disease with Anti-Tumor Necrosis Factor Agent

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The full report is titled “Adalimumab Induction Therapy for Crohn Disease Previously Treated with Infliximab. A Randomized Trial.” It is in the 19 June 2007 issue of *Annals of Internal Medicine* (volume 146, pages 829-838). The authors are W.J. Sandborn, P. Rutgeerts, R. Enns, S.B. Hanauer, J.-F. Colombel, R. Panaccione, G. D’Haens, J. Li, M.R. Rosenfeld, J.D. Kent, and P.F. Pollack.

### What is the problem and what is known about it so far?

Crohn disease is a chronic inflammatory bowel disease. It involves swelling and irritation of the lining of the digestive tract. Symptoms include diarrhea, fever, abdominal pain, weight loss, and fatigue. Patients with Crohn disease usually have signs and symptoms of illness that recur at intervals throughout their lives. Doctors use several drugs to treat recurring bouts of the disease. If symptoms are severe or if patients do not respond to other therapies, doctors may prescribe powerful new drugs called anti-tumor necrosis factor (anti-TNF) agents. Some patients who initially respond to an anti-TNF agent may develop tolerance to that agent, and it will no longer work for them. Other patients may have severe adverse effects that make them stop taking the anti-TNF agent. Few studies tell us whether it is worthwhile to try a second anti-TNF agent in patients who have already tried an anti-TNF agent.

### Why did the researchers do this particular study?

To see whether a different anti-TNF agent, adalimumab, could induce remission in patients with Crohn disease who either lost response to or could not tolerate another anti-TNF agent, infliximab.

### Who was studied?

325 adults with Crohn disease with moderate to severe signs and symptoms of the illness. All patients had responded to or were intolerant of infliximab in the past. At study entry, they either had recurring symptoms despite treatment with infliximab (lost response) or could no longer take it because of adverse effects.

### How was the study done?

Researchers recruited patients from 52 sites in the United States, Canada, and Europe. They randomly assigned patients to receive adalimumab or placebo. Researchers, doctors, and patients did not know who received which treatment. Patients were followed for 4 weeks. The researchers then compared the number of patients with few signs and symptoms of active disease (for example, the number of patients in remission) between groups.

### What did the researchers find?

At 4 weeks, more patients in the adalimumab group were in remission than those in the placebo group (21% vs. 7%). Approximately 1% to 2% of patients in each group discontinued treatment because of an adverse event.

### What were the limitations of the study?

The trial duration was short. It did not test long-term maintenance of response. Also, it did not directly compare different anti-TNF agents to see whether 1 agent was better than another for treating disease.

### What are the implications of the study?

Trying a second anti-TNF agent (adalimumab) may decrease disease activity in some patients with Crohn disease who either lose response to or cannot tolerate another anti-TNF agent (infliximab). Large, long-term trials are needed to see which anti-TNF agents best maintain remission.

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