

Adding Infiximab to the Treatment Regimen for Giant Cell Arteritis

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The full report is titled “Infiximab for Maintenance of Glucocorticosteroid-Induced Remission of Giant Cell Arteritis. A Randomized Trial.” It is in the 1 May 2007 issue of *Annals of Internal Medicine* (volume 146, pages 621-630). The authors are G.S. Hoffman, M.C. Cid, K.E. Rendt-Zagar, P.A. Merkel, C.M. Weyand, J.H. Stone, C. Salvarani, W. Xu, S. Visvanathan, and M.U. Rahman, for the Infiximab-GCA Study Group.

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

Giant cell arteritis (GCA, also called *temporal arteritis*) involves inflammation of large and medium-sized arteries (vasculitis). This condition occurs in elderly people and can lead to sudden blindness. Prompt treatment can prevent blindness. Standard therapy for GCA consists of large doses of steroid drugs (such as prednisone), followed by a gradual decrease in the dose. Patients may need to take a low dose of steroid for many years. Unfortunately, in many patients, symptoms (including muscle ache, fatigue, headache, and change in vision) return as the dose is lowered, or side effects from the steroid develop. Thus, we need better ways to treat GCA. Infiximab is a drug that blocks an inflammatory chemical (called *tumor necrosis factor*, or *TNF*) of the immune system. There is evidence that TNF plays a role in GCA. Earlier reports in small numbers of patients have suggested that blocking the effects of TNF may decrease the amount of steroid needed to treat GCA.

Why did the researchers do this particular study?

To find out whether treatment with infiximab improved outcomes for people with GCA.

Who was studied?

44 patients with newly diagnosed GCA who had responded to steroid treatment.

How was the study done?

The researchers assigned patients at random to receive an intravenous dose of either infiximab or a placebo (a substance that looked like infiximab but contained no active ingredient) at the start of the study; after 2, 6, and 8 weeks; and then every 8 weeks after that. All patients followed a schedule to slowly decrease the steroid dose. If symptoms returned, patients would need to increase the steroid dose and start to decrease the amount they received all over again. The researchers collected information on whether patients' symptoms returned (called *relapse*) and on steroid dose over the course of the study. The researchers planned for the study to last 54 weeks.

What did the researchers find?

Although the study was supposed to continue for 54 weeks, the researchers stopped it after 22 weeks because infiximab did not appear to benefit patients in terms of preventing relapse of symptoms or reducing the amount of steroids required for treatment.

What were the limitations of the study?

The study was small and stopped early, so the researchers could not rule out a small benefit of infiximab. The study was also too small and brief to provide extensive information on the side effects of infiximab.

What are the implications of the study?

Infiximab is unlikely to benefit patients with newly diagnosed GCA.

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