

A Phase 3 Multi-National, Multi-Centre, Double-Blind Placebo-Controlled Parallel Group, 26 Week Study to Assess the Safety and Efficacy of Certolizumab Pegol in the Treatment of Patients With Active Crohn's Disease

Short title: Certolizumab Pegol for the Treatment of Crohn's Disease in Adults

Background	<ul style="list-style-type: none">• Crohn's disease is a chronic inflammatory disorder that affects the intestines. The main symptoms include loose stools (sometimes seen more at night), fever, weight loss, stomach pain and blood loss through the rectum.¹• Crohn's disease is categorised as either mild-to-moderate active disease or moderate-to-severe active disease.¹• In patients with Crohn's disease, C-reactive protein levels (markers for disease severity through inflammation) may be increased.²
Purpose of the study	<ul style="list-style-type: none">• To determine if certolizumab pegol (Cimzia®), a tumour necrosis factor inhibitor, is effective in helping patients with active moderate-to-severe Crohn's disease.• To determine if certolizumab pegol is well tolerated by these patients.
Study participants	<ul style="list-style-type: none">• The study included 660 adult female and male patients aged 18 to 77 years who had active moderate-to-severe Crohn's disease for at least 3 months.
Study design and research methodology	<ul style="list-style-type: none">• The study was conducted in 171 centres across Australia, Austria, Belarus, Belgium, Bulgaria, Canada, Czech Republic, Estonia, Georgia, Germany, Hong Kong, Hungary, Italy, Latvia, Norway, Poland, Russia, Slovenia, South Africa, Sweden, Ukraine and the United States between December 2003 and May 2005. Patients participated in the study for a maximum of 26 weeks.• The study participants were randomly divided into 2 groups at Week 0 and were given either certolizumab pegol or placebo as an injection under the skin at Weeks 0, 2, 4 and then every 4 weeks until Week 24:<ul style="list-style-type: none">○ The patients were further divided within each group based on their C-reactive protein levels: C-reactive protein levels of at least 10 mg per litre and C-reactive protein levels of below 10 mg per litre.• Patients were followed for improvement in symptoms (clinical response) at 6 and 26 weeks and improvement in their overall health condition.• Remission rates were calculated for all the patients. Remission rate is defined as having a Crohn's disease activity index (a tool that measures Crohn's disease symptoms) score of 150 or less.• Side effects were also studied.
Key findings	<ul style="list-style-type: none">• Among patients with C-reactive protein levels of at least 10 mg per litre at baseline, more patients treated with certolizumab pegol showed clinical response compared with patients treated with placebo.• Irrespective of C-reactive protein levels, the rates of clinical response were larger in patients in the certolizumab pegol group compared with patients in the placebo group.• However, remission rates did not improve much with certolizumab pegol.• Side effects were seen in a similar percentage of patients treated with either certolizumab pegol or placebo.• The most common side effects seen in at least 5% of patients in either groups were headache, nasopharyngitis (viral infection of the upper respiratory system), pain in the abdomen, worsening of Crohn's disease, nausea, urinary tract infections, joint pains, fever, vomiting, back pain and pain at the site of injection.• No follow-up trials are foreseen for this study.
Peer-reviewed publication	<p>Sandborn WJ, Feagan BG, Stoinov S, et al. Certolizumab pegol for the treatment of Crohn's disease. <i>N Engl J Med.</i> 2007;357:228-238.</p>

References:

1. Lichtenstein GR, Hanauer SB, Sandborn WJ. Management of Crohn's disease in adults. *Am J Gastroenterol.* 2009;104:465-483.
2. Kiss LS, Papp M, Lovasz BD, et al. High-sensitivity C-reactive protein for identification of disease phenotype, active disease, and clinical relapses in Crohn's disease: a marker for patient classification? *Inflamm Bowel Dis.* 2012;18:1647-1654.

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