

A Phase 3 Multicentre, Double Blind, Placebo-Controlled, Parallel Group 52-Week Study to Assess the Efficacy and Safety of 2 Dose Regimens of Lyophilised Certolizumab Pegol as Additional Medication to Methotrexate in the Treatment of Signs and Symptoms and Preventing Structural Damage in Patients With Active Rheumatoid Arthritis who Have an Incomplete Response to Methotrexate

Short title: Certolizumab Pegol for the Treatment of Rheumatoid Arthritis in Adults

Background	<ul style="list-style-type: none">Rheumatoid arthritis is a chronic systemic disorder that causes the immune system, which usually fights infection, to rapidly attack the joints. The result is a painful inflammation, known as arthritis, and a subsequent joint damage that can be disabling. This slows down the patients' activities, and ultimately leads to a substantial loss of functioning and mobility.^{1,2}
Purpose of the study	<ul style="list-style-type: none">To determine if treatment of patients with rheumatoid arthritis with a combination of certolizumab pegol (Cimzia®, a tumour necrosis factor inhibitor) and methotrexate is helpful in improving symptoms and physical function, as well as slowing down structural damage to the joints as seen in x-rays (i.e., radiographic progression).To determine if the combination of certolizumab pegol and methotrexate is well tolerated by these patients.
Study participants	<ul style="list-style-type: none">The study included 982 adult male and female patients aged 18 years or more with rheumatoid arthritis whose symptoms did not improve with methotrexate treatment alone.
Study design and research methodology	<ul style="list-style-type: none">The study was conducted in 147 centres in Argentina, Australia, Belgium, Bulgaria, Canada, Chile, Croatia, Czech Republic, Estonia, Finland, France, Hungary, Israel, Latvia, Lithuania, Mexico, New Zealand, Russia, Serbia, Slovakia, Ukraine and the United States between February 2005 and September 2006. Patients participated in the study for a maximum of 13 months.The study participants were randomly divided into 3 groups and were given either of the doses of certolizumab pegol or placebo as an injection under the skin every 2 weeks.<ul style="list-style-type: none">All patients continued taking methotrexate.The patients were followed after 24 and 52 weeks for improvement in symptoms and physical function, and for radiographic progression of the disease.Side effects were also studied.
Key findings	<ul style="list-style-type: none">More number of patients in the certolizumab pegol plus methotrexate group compared with placebo and methotrexate group showed:<ul style="list-style-type: none">Improvement in symptoms of rheumatoid arthritis from week 1 to 52.Improvement in physical function.Less radiographic progression.Side effects were mostly mild to moderate in intensity. More number of patients treated with certolizumab pegol had side effects compared with placebo.<ul style="list-style-type: none">The most common side effects reported in at least 5% of patients were headache, high blood pressure, back pain, urinary tract infections, nasopharyngitis (viral infection of the upper respiratory system) and upper respiratory tract infection.A follow-up study conducted over several years further assessed the safety and efficacy of certolizumab pegol [NCT00175877].
Peer-reviewed publication	<p>Keystone E, Heijde D, Mason D, Jr., et al. Certolizumab pegol plus methotrexate is significantly more effective than placebo plus methotrexate in active rheumatoid arthritis: findings of a fifty-two-week, phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study. <i>Arthritis Rheum.</i> 2008;58:3319-3329.</p>

References:

- Choy E. Understanding the dynamics: pathways involved in the pathogenesis of rheumatoid arthritis. *Rheumatology (Oxford)*. 2012;51 Suppl 5:v3-v11.
- McInnes IB, Schett G. The pathogenesis of rheumatoid arthritis. *N Engl J Med*. 2011;365(23):2205-2219.

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