

24-Week Study to Assess the Efficacy and Safety of Certolizumab Pegol in Combination With Methotrexate Compared to Methotrexate Alone in the Treatment of the Signs and Symptoms of Patients With Rheumatoid Arthritis who are Partial Responders 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 the combination of certolizumab pegol (Cimzia®, a tumour necrosis factor inhibitor) and methotrexate can be helpful in improving symptoms of rheumatoid arthritis in patients who do not have enough improvement with methotrexate alone.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 247 adult female and male patients aged 18 to 75 years with rheumatoid arthritis whose symptoms did not improve enough with methotrexate treatment alone.
Study design and research methodology	<ul style="list-style-type: none">The study was conducted in 43 centres across Austria, Belgium, Czech Republic, Germany, Ireland, UK and the United States between October 2002 and January 2004. Patients participated in the study for a maximum of 9 months.The study participants were equally divided into 2 groups and given either certolizumab pegol or placebo as an injection under the skin every 4 weeks for 24 weeks.<ul style="list-style-type: none">Patients in both the treatment groups continued taking methotrexate.The patients were followed after 24 weeks to find out the number of patients in each group whose symptoms and quality of life were better.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 patients in the placebo plus methotrexate group showed:<ul style="list-style-type: none">Improvement in symptoms of rheumatoid arthritis such as pain.Decrease in the number of swollen and tender joints from week 1 to week 24.The number of side effects related to the study medication and serious side effects was similar in both groups. Most side effects were mild to moderate in intensity.<ul style="list-style-type: none">The most common side effects seen in at least 2 patients in either of the treatment groups were nasopharyngitis (viral infection of the upper respiratory system), headache, fatigue, back pain, upper respiratory tract infection, herpes simplex, lower respiratory tract infection and sinusitis.A follow-up study conducted over several years further assessed the safety and efficacy of certolizumab pegol [NCT00160693].
Peer-reviewed publication	<p>Choy E, McKenna F, Vencovsky J, et al. Certolizumab pegol plus MTX administered every 4 weeks is effective in patients with RA who are partial responders to MTX. <i>Rheumatology (Oxford)</i>. 2012;51:1226-1234.</p>

References:

- Choy E. Understanding the dynamics: pathways involved in the pathogenesis of rheumatoid arthritis. *Rheumatology (Oxford)*. 2012;51 Suppl 5:v3-11.
- McInnes IB, Schett G. The pathogenesis of rheumatoid arthritis. *N Engl J Med*. 2011;365(23):2205-2219.

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