A Phase 3, Multicentre, Double–Blind, Placebo–Controlled, Parallel-Group, 24–Week Study to Assess the Efficacy and Safety of 2 Dose Regimens of Liquid Certolizumab Pegol as Additional Medication to Methotrexate in the Treatment of Signs and Symptoms of Rheumatoid Arthritis and in Prevention of Joint 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	• 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	• 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	• The study included 619 adult female and male patients aged 18 years or more with rheumatoid arthritis whose symptoms had not improved with methotrexate treatment alone.
Study design and research methodology	• The study was conducted in 76 centres across Bulgaria, Croatia, Czech Republic, Estonia, Israel, Latvia, Lithuania, Poland, Russia, Serbia, Slovakia, Ukraine and the United States between June 2005 and September 2006. Patients participated in the study for a maximum of 6 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. o All patients continued taking methotrexate. • The patients were followed after 24 weeks for improvement in symptoms and physical function, and slowing down of radiographic progression. • Side effects were also studied.
Key findings	• More patients in the certolizumab pegol plus methotrexate groups compared with placebo and methotrexate group showed: o Decrease in symptoms of rheumatoid arthritis from week 1 to week 24. o Improvement in physical function. o Slowing down of radiographic progression. • Side effects were similar in all the groups. Most side effects were mild to moderate in intensity. o The most common side effects reported in at least 3% of patients were urinary tract infections, respiratory infections, headache, presence of bacteria in the urine, nasopharyngitis (viral infection of the upper respiratory system), rheumatoid arthritis, high blood pressure, presence of blood in the urine and increase in various enzyme levels. • A follow-up study conducted over several years further assessed the safety and efficacy of certolizumab pegol [NCT00160641].
Peer-reviewed publication	Smolen J, Landewe RB, Mease P, et al. Efficacy and safety of certolizumab pegol plus methotrexate in active rheumatoid arthritis: the RAPID 2 study. A randomised controlled trial. *Ann Rheum Dis.* 2009;68:797-804.

References:

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

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