

Phase 3, Multicentre, Randomised, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Certolizumab Pegol in Subjects with Adult-Onset Active and Progressive Psoriatic Arthritis

[on-going study]

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

Background¹	<ul style="list-style-type: none">Psoriatic arthritis is an inflammatory condition of the joints and the skin. The symptoms mainly include joint problems, such as stiffness, pain, tenderness and swelling, of the hands and feet. The patients may also have problems with body movements, experience eye redness, and suffer from skin and nail diseases.
Purpose of the study	<ul style="list-style-type: none">To determine if certolizumab pegol (Cimzia[®]), a tumour necrosis factor inhibitor, is helpful in improving the symptoms in patients with psoriatic arthritis.To determine if certolizumab pegol/rotigotine is well tolerated by these patients.
Study participants	<ul style="list-style-type: none">The study includes 409 adult female and male patients aged 18 years or more who had psoriatic arthritis for at least 6 months.These patients have active disease and had also failed to show improvement in symptoms with at least 1 previous treatment, which may have included a different tumour necrosis factor inhibitor.
Study design and research methodology	<ul style="list-style-type: none">The study is being conducted in 92 centres across Argentina, Belgium, Brazil, Canada, Czech Republic, France, Germany, Hungary, Ireland, Italy, Mexico, Poland, Spain, UK and the United States. It was started in March 2010 and is expected to end in August 2015. Patients are participating in the study for a maximum of 54 months.The study participants were equally divided into 3 groups and received injections of either 2 different doses of certolizumab pegol or placebo.In the first part of the study, the patients were followed after 12 and 24 weeks to assess improvements in their joint, skin and nail disease as well as pain and ability to perform daily physical activities.Side effects were also studied.
Key findings (up to Week 24)	<ul style="list-style-type: none">More patients in the certolizumab pegol group compared with placebo group showed:<ul style="list-style-type: none">Improvement in symptoms of psoriatic arthritis from week 1 to week 24.Improvements in joint pain and discomfort.Improvements in condition of the skin and nails.This improvement in symptoms was also seen in patients who had previously been treated with tumour necrosis factor inhibitors.Side effects, serious side effects and infections were similar in both placebo and certolizumab pegol groups. Most side effects were mild to moderate.<ul style="list-style-type: none">The most common side effects reported in at least 3% of patients in either of the treatment groups were the nasopharyngitis (viral infection of the upper respiratory system), infections of the respiratory system, loose or watery stools and headache.
Peer-reviewed publication	<p>Mease PJ, Fleischmann R, Deodhar AA, et al. Effect of certolizumab pegol on signs and symptoms in patients with psoriatic arthritis: 24-week results of a Phase 3 double-blind randomised placebo-controlled study (RAPID-PsA). <i>Ann Rheum Dis</i>. 2014 Jan 1;73 (1):48-55.</p>

Reference:

- Huynh D, Kavanaugh A. Psoriatic arthritis: current therapy and future directions. *Expert Opin Pharmacother*. 2013;14(13):1755-1764.

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