

Phase 3, Multicentre, Randomised, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy And Safety of Certolizumab Pegol in Subjects With Active Axial Spondyloarthritis

[on-going study]

Short title: *Certolizumab Pegol for the Treatment of Axial Spondyloarthritis in Adults*

Background¹

- Axial spondyloarthritis is an inflammatory disorder affecting the spine, joints at the base of the spine, and peripheral joints. The main symptoms include chronic low back pain, pain and swelling in the joints, and tiredness; it can also be associated with other extra-articular manifestations as these are important for the diagnosis of the disease.
- Axial spondyloarthritis comprises two subgroups:
 - Non-radiographic axial spondyloarthritis: X-ray reports do not show damage of the joints at the base of the spine.
 - Ankylosing spondylitis: X-ray reports show damage of the joints at the base of the spine.
- Although both ankylosing spondylitis and non-radiographic axial spondyloarthritis have a similar frequency of occurrence, the latter condition is less well recognised. As it can take many years for structural changes to develop, if at all, it frequently takes many years to diagnose axial spondyloarthritis which may result in delayed treatment.

Purpose of the study

- To determine if treatment with certolizumab pegol (Cimzia®), a tumour necrosis factor inhibitor, is helpful in controlling the symptoms of patients suffering from axial spondyloarthritis.
- To determine if certolizumab pegol is well tolerated by these patients.

Study participants

- The study includes 325 adult male and female patients aged 18 years or older with axial spondyloarthritis who were experiencing back pain for at least 3 months.
- These patients had only minimal improvement in symptoms with at least 1 non-steroidal anti-inflammatory medicine.

Study design and research methodology

- The study is being conducted in 83 centres across Argentina, Belgium, Brazil, Canada, Czech Republic, France, Germany, Hungary, Mexico, Netherlands, 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 this study for a maximum of 51 months.
- The study participants were equally divided into 3 groups and randomised to receive injections of either 2 different doses of certolizumab pegol or placebo.
- Patients were followed at multiple time points during the first 24-week phase of the study to assess improvement in disease activity.
- Side effects were also studied.

Key findings (up to Week 24)

- The disease burden of both non-radiographic axial spondylitis and ankylosing spondylitis were similar.
- In all patients, treatment with certolizumab pegol compared with placebo showed:
 - Improvement in symptoms from week 1 to week 24.
 - Decreased back pain.
- The treatment effect was similar in both the non-radiographic axial spondylitis and the ankylosing spondylitis subpopulations compared to placebo.
- Side effects were similar in the placebo and certolizumab pegol groups. Most of the side effects were mild to moderate in intensity.
 - The most common side effects (seen in at least 5% of patients treated with either dose of certolizumab pegol) were nasopharyngitis (viral infection of the upper respiratory system), headache, infections of the respiratory system, increase in blood creatinine phosphokinase levels and injection site reactions.

Peer-reviewed publication

[Landewe R, Braun J, Deodhar A, et al. Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-controlled Phase 3 study. *Ann Rheum Dis.* 2014;73:39-47.](#)

Reference:

1. Rudwaleit M, Sieper J. Referral strategies for early diagnosis of axial spondyloarthritis. *Nat Rev Rheumatol* 2012;8:262–268.

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