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Are less expensive "biosimilar" drugs as effective at treating ankylosing spondylitis?

Ankylosing spondylitis (AS) is a type of arthritis caused by inflammation, in which the main symptom is back pain. When a substance called tumour necrosis factor (TNF) is over-active in the body, it causes inflammation and damage to bones, cartilage and surrounding tissue. Anti-TNF treatments, including an antibody called Remicade (reference infliximab), block the action of TNF and can reduce inflammation. These so-called 'biologic drugs' are difficult to produce and are therefore expensive. Because of this, patients with AS or other immune-related diseases who may benefit from this type of treatment are not always offered it. 'Biosimilar infliximab', also known by its project name CT-P13 and brand names Remsima and Inflectra, is a similar but less expensive alternative to Remicade and has been tested side-by-side with Remicade in a number of clinical trials.

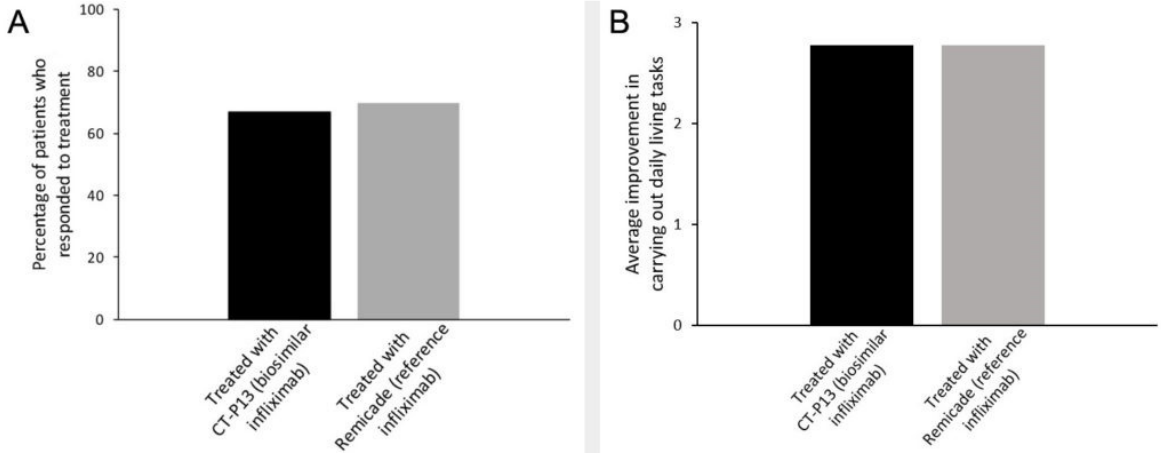

Fig. 1. A. The proportion of patients with a 20% improvement in the signs and symptoms of AS* was very similar between those taking CT-P13 (biosimilar infliximab) and those taking Remicade (reference infliximab). B. The average improvement in carrying out daily living tasks** was very similar for patients taking CT-P13 (biosimilar infliximab) and those taking Remicade (reference infliximab). *Patient response measured by ASAS20 at week 54 (after 54 weeks of treatment with CT-P13 or Remicade). **Patient response measured as decrease in difficulty with respect to baseline scores by Bath Ankylosing Spondylitis Functional Index at week 54 (after 54 weeks of treatment with CT-P13 or Remicade).

One such clinical trial was a large multinational study that investigated whether CT-P13 was as effective and safe as Remicade at treating AS. The study, called PLANETAS, involved 250 patients from 10 different countries. Patients took either CT-P13 or Remicade for 1 year and improvements in the signs and symptoms of AS were monitored. The results showed that there was no difference between the patients taking CT-P13 and those taking Remicade in the percentage who had an improvement in signs and symptoms of AS. Figure 1A shows the percentage of patients taking CT-P13 or Remicade who experienced a 20% improvement in the signs and symptoms of AS.

Patients taking CT-P13 or Remicade also completed a questionnaire rating the level of difficulty they experienced in carrying out daily living tasks (e.g. putting on socks, getting out of a chair). Figure 1B shows the improvements in these measures for patients taking CT-P13 and those taking Remicade.

The study also showed that CT-P13 was as safe as Remicade. Most of the side effects that did occur were mild or moderate.

In conclusion, the results from the PLANETAS study demonstrated that over a 1-year period, CT-P13 was as effective and safe as Remicade for treating AS. Being a biosimilar, CT-P13 is less expensive than Remicade and therefore may make effective AS treatment accessible to more patients, and also provide budget savings to healthcare systems.

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Publication

Comparable long-term efficacy, as assessed by patient-reported outcomes, safety and pharmacokinetics, of CT-P13 and reference infliximab in patients with ankylosing spondylitis: 54-week results from the randomized, parallel-group PLANETAS study.
Park W, Yoo DH, Jaworski J, Brzezicki J, Gnylorybov A, Kadinov V, Sariego IG, Abud-Mendoza C, Escalante WJ, Kang SW, Andersone D, Blanco F, Hong SS, Lee SH, Braun J.
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