

Study shows efficacy of new rheumatoid arthritis drug

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(Medical Xpress) -- A new study involving researchers from Karolinska Institutet demonstrates the efficacy of Tofacitinib, a new drug for rheumatoid arthritis. According to the study, which is published in The New England Journal of Medicine, the drug is just as effective as biological medicines, but unlike them can be taken in tablet form.

The present study was a phase III trial of Tofacitinib, and included 717 people with rheumatoid arthritis. The participants were divided into three groups, who received either a high or low dose of the drug, the already approved substance <u>Adalimumab</u>, or a placebo. Adalimumab is a biological drug, one of a group of substances that were introduced onto the market at the end of the 1990s.

After six months, the patients who had been given Tofacitinib showed most improvement according to the ACR20 criteria, a composite assessment of the patients symptom profile. Over 50 per cent of those who had received Tofacitinib had gained some symptom relief, compared with 47 and 27 per cent in the Adalimumab and placebo groups respectively.

"The new substance, Tofacitinib, has thus proved to have an efficacy on par with the biological drugs," says Ronald van Vollenhoven, professor of clinical therapy research, <u>inflammatory diseases</u> at Karolinska Institutet. "This finding is very welcome as we need more efficacious drugs for treating rheumatoid arthritis."



The study also showed that Tofacitinib carries the risk of several possible adverse reactions, including <u>gastrointestinal disorders</u>, hepatopathy, a decrease in white and <u>red blood cells</u>, raised cholesterol levels and increased sensitivity to infection.

"However, none of these adverse reactions was very common and most patients tolerated the treatment well," says Professor van Vollenhoven.

In Sweden, it is estimated that 60,000 people have rheumatoid arthritis (RA), which causes pain, swelling and stiffness in the joints, and which often ultimately leads to pronounced <u>physical disability</u>. The introduction of biological drugs on the market brought great advances in the treatment of RA, since roughly two thirds of the patients are not adequately helped by older medicines.

"But then again, not everyone responds to treatment with the biological drugs," adds Professor van Vollenhoven. "They're also costly and must be taken as infusions or injections. We expect the production of Tofacitinib, a conventional chemical drug, to be cheaper, giving us another drug to use in the battle against <u>rheumatoid arthritis</u>."

The study was a collaboration between clinics in seven countries and was financed by Pfizer, which has applied for a licence to sell Tofacitinib in the USA and Europe.

More information: Ronald van Vollenhoven, Roy Fleischmann, Stanley Cohen, Eun Bong Lee, Juan A. García Meijide, Sylke Wagner, Sarka Forejtova, Samuel H. Zwillich, David Gruben, Tamas Koncz, Gene Wallenstein, Sriram Krishnaswami, John Bradley, Bethanie Wilkinson, Tofacitinib or Adalimumab versus Placebo in Rheumatoid Arthritis, *New England Journal of Medicine*, print issue 9th August 2012.



Provided by Karolinska Institutet

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