New drug shows promising results for psoriatic arthritis

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Psoriatic arthritis affects about 11 percent of patients with psoriasis. Anti-tumor necrosis factor α (anti-TNFα) agents, which block signaling molecules that induce inflammation, improve the symptoms of psoriatic arthritis. Golimumab is a new human monoclonal antibody that works against TNFα and has been shown to be beneficial within two weeks of the first subcutaneous injection in a phase II rheumatoid arthritis trial. A new phase III, multicenter, randomized, double-blind, placebo-controlled trial, the largest of its kind to be completed with a biologic agent to treat psoriatic arthritis and the first placebo-controlled study evaluating the effect of a TNF inhibitor on nail psoriasis, found that golimumab significantly improved active psoriatic arthritis and associated skin and nail psoriasis. The study was published in the April issue of *Arthritis & Rheumatism*.

Led by Arthur Kavanaugh of the University of California San Diego in La Jolla, CA the study involved 405 patients with active psoriatic arthritis even after having taken disease-modifying antirheumatic drugs or nonsteroidal anti-inflammatory drugs. Patients were randomized to receive subcutaneous injections of placebo, golimumab 50 mg, or golimumab 100 mg every four weeks for 24 weeks. Patients with less than 10 percent improvement in swollen and tender joints at week 16 were switched from placebo to 50 mg golimumab or from 50 mg to 100 mg.

The primary end point of the study was the proportion of patients who met the American College of Rheumatology 20 percent improvement

criteria (ACR20 response) at week 14. This response included at least a 20 percent improvement in swollen and tender joint counts and other measures such as pain, disease activity, physical function, and C-reactive protein. ACR50 and ACR70 responses were defined by at least 50 percent and at least 70 percent improvement.

The results showed that golimumab was efficacious and generally well tolerated. An ACR20 response was achieved at week 14 by 51 percent of patients receiving 50mg and 45 percent of those receiving 100mg, compared with 9 percent of placebo-treated patients. In addition, significantly more golimumab-treated patients than placebo-treated patients achieved ACR50 and ACR70 responses and those who initially showed little improvement and switched from placebo to golimumab or increased their dosage also showed improvement. Patients treated with the drug had significant improvement in physical function and health-related quality of life, as well as significant improvement in enthesitis, an inflammation where muscles attach to bones. In addition to improving arthritic symptoms, golimumab also improved psoriasis symptoms: 40 percent of the 50 mg group and 58 percent of the 100 mg group had at least 75 percent improvement in psoriasis symptoms, compared with 3 percent of the placebo group. "The safety profile of golimumab in psoriatic arthritis was similar to other anti-TNF agents that have been studied in this disease. Subcutaneous administrations were well tolerated. Only a small number of patients had injection site reactions, which were mostly mild.

This was also the first placebo-controlled study evaluating the effect of an anti-TNFα on nail psoriasis, which affected about 70 percent of the patients involved in the study. Significant improvements in nail symptoms were seen in those treated with golimumab as early as week 14 and were maintained or improved through the end of the study period.

The authors conclude that "subcutaneous golimumab (at doses of 50 mg and 100 mg) administered every 4 weeks significantly improved active psoriatic arthritis and associated skin disease." Longer-term data on golimumab's efficacy and safety will be reported in the future.

More information: Golimumab, a New Human Tumor Necrosis Factor α Antibody, Administered Every Four Weeks as a Subcutaneous Injection in Psoriatic Arthritis," Arthur Kavanaugh, Iain McInnes, Philip Mease, Gerald G. Krueger, Dafna Gladman, Juan Gomez-Reino, Kim Papp, Julie Zrubek, Surekha Mudivarthy, Michael Mack, Sudha Visvanathan, Anna Beutler, Arthritis & Rheumatism, April 2009. http://www3.interscience.wiley.com/journal/76509746/home

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