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Effects of Oral Administration of Type II Collagen on Rheumatoid Arthritis

Rheumatoid arthritis is an inflammatory synovial disease thought to involve T cells reacting to an antigen within the joint. Type II collagen is the major protein in articular cartilage and is a potential autoantigen in this disease. Oral tolerization ito autoantigens suppresses animal models of T cells-mediated autoimmune disease, including two models of rheumatoid arthritis. *In this randomized, double-blind trial involving 60 patients with severe, active rheumatoid arthritis, a decrease in the number of swollen joints and tender joints occurred in subjects fed chicken type II collagen for 3 months but not in those that received a placebo. Four patients in the collagen group had complete remission of the disease. No side effects were evident.* These data demonstrate linical efficacy of an oral tolerization approach for rheumatoid arthritis.

- Current treatments are inadequate in that they only partially control established rheumatoid arthritis. They also have side effects that limit use early in the disease process and interfere with prolonged administration.
- Subjects were taken off their immune-suppressive and disease-modifying drugs consisting of methotrexate, 6-mercaptopurine, azathioprine, or auranofin and fed 0.1 mg of solubilized type II collagen daily for 1 month and then switched to 0.5 mg for the next 2 months.
- Six of the 10 patients experienced a substantial clinical response, defined by a greater than 50% improvement in both swollen and tender joint counts.
- A complete response, that is, disease remission with discontinuation of nonsteroidal anti-inflammatory drug (NSAID), occurred in one patient previously on methotrexate and continued for 26 months. There were no adverse effects.
- Among the collagen patients, the decline in the number of swollen joints, tender joints, and joint-swelling indices were all significant. Four of the collagen patients (14%), as compared with none in the placebo group, had complete resolution of the disease.
- Stability or improvement while patients were off immunosuppressives occurred in the collagen group, whereas patients in the placebo group tended to deteriorate.

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- No side effects or significant changes in laboratory values, including rheumatoid factor and antibodies to type II collagen, were noticed.
- All patients in the phase II trial and open-label trial had collagen discontinued after 3 months. Four patients in the pilot study who improved while on collagen experienced relapse about 3 months after cessation of therapy followed by benefit with reinitiation of collagen.
- It therefore appears that additional administration is required to maintain clinical effects of oral tolerance.

Although initial clinical efficacy of oral collagen has been shown, questions concerning optimum dosing and long-term control of disease remain. Nontheless, *this study demonstrates the therapeutic efficacy of oral tolerance for a human autoimmune disease and provides the foundation for the development of oral collagen as an easily administered non-toxic treatment for rheumatoid arthritis.*

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