Clinical Trial ID:

NCT00000401

Title:

Oral Collagen for Rheumatoid Arthritis

Summary:

Rheumatoid arthritis (RA) is an autoimmune disease characterized by swelling and inflammation of the joints. In RA, the immune system attacks a person's own cells inside joints, eventually leading to joint damage and disability. This study will determine if oral bovine type II collagen (bovine CII) will lead to decreased joint inflammation in RA patients.

Detailed Description:

RA is an inflammatory disease that causes pain, swelling, stiffness, and loss of function in the joints. The study will evaluate the effects of using oral bovine CII on RA patients by assessing the levels of inflammation markers such as interferon gamma (IFN-gamma), interleukin-10 (IL-10), and transforming growth factor beta (TGF-beta). This study is a multicenter clinical trial to be conducted at the University of Tennessee, Memphis (the lead center) and the West Tennessee Medical Specialty Clinic (a

collaborating site).

Patients enrolled will be allowed to continue a constant dose of disease-modifying anti-rheumatic drugs (DMARDs) and prednisone less than or equal to 7.5 mg/day. Patients will be randomly assigned to one of two groups. The low dose group will receive 30 mcg daily for 10 weeks, then 50 mcg daily for 10 weeks, followed by 70 mcg daily for 10 more weeks; the high dose group will receive 90 mcg daily for 10 weeks, then 100 mcg daily for 10 weeks, followed by 130 mcg daily for 10 more weeks. Blood will be collected at screening and at Weeks 10, 20, and 30. Blood will be analyzed for indicators of inflammation.

Note: this trial is no longer being conducted as an intervention trial. Accrual has been discontinued, although patients previously enrolled are still being followed.

Eligibility Criteria:

Note: accrual into this trial has been discontinued, but patients previously enrolled are still being followed.

Inclusion Criteria:

- **Clinically stable RA and unlikely to require adjustment of doses of DMARDs, NSAIDs,**
  prednisone, or anti-TNFα therapies for the treatment phase of the study

- **Meets American College of Rheumatology (ACR) 1988 revised criteria for RA**

- **Onset of disease at age 16 or older**

- **Onset of disease at least 3 months prior to enrollment**

- **PBMC - IFNγ - α1(II)/PBS stimulation index greater than or equal to 1.5 in 6 months**
  prior to baseline visit

- **Agree to discontinue herbal remedies described in this protocol**

- **Agree to use acceptable forms of contraception**

Exclusion Criteria:

- **Participation in another clinical research study involving the evaluation of another**
  investigational drug within 90 days prior to study entry

- **Currently taking greater than 7.5 mg prednisone daily**

- **Intra-articular corticosteroid injections within 30 days prior to study entry**

- **Concurrent serious medical condition which, in the opinion of the investigator,**
  makes the patient inappropriate for the study

- **Pregnancy**

- **Beef allergy**

- **Use of fish oil within 4 weeks of study entry**

- **Previous use of auranofin or cyclophosphamide (all other DMARDs are allowed)**

- **Previous autologous or heterologous stem cell transplantation**

- **Active malignancy or past treatment consisting of antineoplastic drugs or total**
  lymphoid irradiation

- **Intolerance to citrus juices or colorless carbonated beverages**

Gender:

All

Minimum Age:

18 Years

Maximum Age:

80 Years

Phase:

Phase 2

Conditions:

- Rheumatoid Arthritis

Interventions:

- Oral bovine type II collagen

Locations:

- The Arthritis Clinic of Jackson, PLLC, Jackson, Tennessee

- University of Tennessee, Memphis, Memphis, Tennessee