**Glucosamine/Chondroitin Arthritis Intervention Trial (GAIT)**

**Effectiveness of glucosamine/chondroitin in treating osteoarthritis of the knee**

**The Topic**

**The Study**
Conducted in 16 U.S. centers, the GAIT trial was a randomized, double-blind, placebo- and celecoxib-controlled trial. This trial included 1,583 patients with symptomatic knee arthritis. Patients were randomized into one of five treatment arms: glucosamine hydrochloride (n=317), chondroitin sulfate (n=318), combination glucosamine/chondroitin (n=317), celecoxib (n=318) or placebo (n=313). Acetaminophen was permitted for rescue analgesia in doses up to 4,000 mg/day. Patients were stratified according to mild knee pain (n=1,229) and moderate-to-severe knee pain (n=354).

**The Results**
After 24 weeks of treatment, glucosamine hydrochloride, chondroitin sulfate and the combination of both agents failed to show a statistically significant difference defined as a 20 percent reduction in knee pain when compared to baseline data. Statistical significance was noted in the celecoxib treatment group when compared to placebo, validating the positive control.

The moderate-to-severe subset of patients randomized to the combination group achieved statistically significant pain relief when compared to placebo. It is important to note that the trial was not powered to detect a difference between the mild knee pain group and the moderate to severe group. Further trials designed with appropriate power are needed to validate these findings.

**Facts to Consider**
- The trial was sponsored by the NIH and required over $12.5 million to complete.
- Purity, potency and integrity of the supplements were accounted for.
- A 60.1 percent response rate was noted in the placebo group.
- The attrition rate of the study was 20.5 percent.
- Glucosamine hydrochloride was used instead of the glucosamine sulfate formulation.
- The study was not powered to detect a difference between mild and moderate/severe pain groups.
- Treatment groups were designed only to be compared to placebo. The design of the trial does not permit comparisons between the celecoxib group and the combination arm or each separate ingredient.

**What to Tell Your Patients**
- Counsel patients that dietary supplements are not without side effects and are not regulated with the same scrutiny as prescription medications.
- Available clinical evidence evaluating glucosamine and chondroitin has produced mixed findings.
- Encourage patients to talk with their physician to develop a comprehensive treatment plan for the treatment and management of osteoarthritis including the role of glucosamine and chondroitin.
- Four to six weeks of therapy with glucosamine and chondroitin may be required to see a reduction of symptoms. Three months is considered an adequate trial.
• Within clinical trials the glucosamine sulfate formulation has achieved the most promising outcomes with available clinical trials. Although it is not as widely available, encourage the use of the sulfate formulation when possible.

• Substantial variation between products has been noted when product labeling and active ingredients of supplements containing glucosamine and chondroitin have been compared.

ONGOING RESEARCH
Further research is ongoing to evaluate the structure-modification effect of glucosamine and chondroitin. Approximately one-half of the participants in the GAIT trial have continued therapy for an additional 18 months. Radiographic images will be compared to evaluate changes in the knee joint.

RESOURCES
GAIT Trial
http://content.nejm.org/cgi/content/short/354/8/795

Editorial
http://content.nejm.org/cgi/content/full/354/8/858

NIH News Brief

National Center for Complementary and Alternative Medicine
Backgrounder – Questions and Answers: NIH Glucosamine/ chondroitin Arthritis Intervention Trial (GAIT)

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This publication is intended to provide key practical information regarding this drug product in a brief format. It does not contain sufficient information upon which to base formulary or other medication use policy decisions.