

Serum Shots Show Promise for Knee Osteoarthritis

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PRAGUE — Intra-articular injections of autologous conditioned serum reduced the symptoms of knee osteoarthritis significantly more than did either saline or hyaluronan injections in the first controlled clinical trial of the therapy, Dr. Carsten Moser reported at the 2006 World Congress on Osteoarthritis.

"This is a completely different approach to the treatment of osteoarthritis," said Dr. Moser, a physician at University Hospital Düsseldorf, Germany, and also an advisor to the company that markets Orthokine, the product used to condition the serum.

The therapy, originally marketed as IRAP to treat lameness in racehorses, is used by more than 400 physicians in Europe to enhance muscle healing in humans, he said at the meeting, which was sponsored by the Osteoarthritis



ORTHOKINE AG

Conditioned serum injections, found to ease knee OA pain, involve the incubation of patients' venous blood with medical glass beads.

Research Society International. "It does not require approval in Europe because it involves autologous serum, which is drawn and prepared by the physician," he said in an interview. The company is currently facing distribution

problems in the United States, and it is unclear if the therapy will require FDA approval, he added.

Serum conditioning involves incubation of patients' venous blood with medical grade glass beads, Dr. Moser said. Previously

published work has shown that this incubation procedure elicits a rapid increase in the serum's synthesis of several anti-inflammatory cytokines (Inflamm. Res. 2003;52:404-7).

"Peripheral blood leukocytes produce elevated amounts of endogenous anti-inflammatory cytokines such as interleukin-1 receptor antagonist," he said. The conditioned serum is then injected into the affected joint.

The trial involved 345 patients, average age 57 years, with radiological evidence of knee osteoarthritis and pain greater than 50 points on a 100-point visual analog scale. After blood was drawn from all patients, they were randomized, to ensure blinding, to intra-articular injections of either autologous conditioned serum (ACS), hyaluronan (HA), or saline twice a week for 3 weeks.

The outcomes were assessed at 7, 13, and 26 weeks after the last injection, using patient-adminis-

tered outcome instruments of pain measurement including the Western Ontario and McMaster Osteoarthritis index (WOMAC), the Visual Analog Scale (VAS), and a health-related quality-of-life measure (SF-8).

"Pain was significantly reduced in all three groups and quality of life was increased. However, the positive therapeutic responses to ACS were stronger, compared to the other treatment modalities," he said. "The magnitude of improvement in the ACS group was significantly higher and persisted for months after the last injection. Compared with ACS, the mean reduction in pain was half in the other treatment groups."

Adverse events were minor in all groups and were confined to localized pain and swelling from the injection. This occurred in 23% of the ACS group, compared with 28% of the saline group and 38% of the HA group, Dr. Moser noted. ■