Objective: Osteoarthritis (OA) is prevalent and difficult to treat. Autologous conditioned serum (ACS), marketed under the trade name Orthokine, is a novel, injectable antiarthritic derived from the patient’s own blood. The present study is the first time ACS has undergone a controlled clinical trial.

Method: We investigated 376 patients with knee OA in a prospective, randomized, patient- and observer-blinded, placebo-controlled trial using an intention-to-treat analysis (ITT). The clinical effects of ACS were compared to hyaluronan (HA) and saline (placebo) as assessed by patient-administered outcome instruments (Western Ontario and McMaster Universities osteoarthritis index, global patient assessment, visual analog scale, Short-Form 8) after 7, 13 and 26 weeks. After 104 weeks an observer-blinded follow-up was carried out. Frequency and severity of adverse events were used as safety parameters.

Results: In all treatment groups, intra-articular injections produced a reduction in symptoms as well as an improvement in quality of life. However, the effects of ACS were significantly superior to those of HA and saline for all outcome measures and time points, and improvements were clinically relevant; there were no differences between the effects of HA and saline. The frequency of adverse events was comparable in the ACS and saline groups, but higher in the HA group.

Conclusion: The data demonstrate that ACS injection considerably improves clinical signs and symptoms of OA. It remains to be determined whether ACS is disease-modifying, chondroprotective, or chondroregenerative.

Key words: Autologous conditioned serum (ACS), Orthokine, Orthokin, Osteoarthritis, Interleukin-1 receptor antagonist (IL-1Ra), Intra-articular injections, Hyaluronan.