

[THU0411] EFFICACY AND SAFETY OF SODIUM HYALURONATE IN HIP OSTEOARTHRITIS. A RANDOMISED, DOUBLE-BLIND, LIDOCAINE-CONTROLLED, MULTICENTRE STUDY WITH A 12-MONTH FOLLOW-UP

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Objectives: To evaluate the efficacy, safety and duration of intra-articular injections of sodium hyaluronate and lidocaine in patients with hip osteoarthritis (OA).

Methods: The study was a randomised, lidocaine-controlled, multicentre, prospective study. At the end of the 24-week double-blind phase, patients in the sodium hyaluronate (SH) group were followed up in an open-label extension study phase up to Week 48. Patients aged 40 to 70 years with Kellgren-Lawrence radiologic grade I to III hip OA according to the criteria of the American College of Rheumatology (ACR) were randomised to receive an intra-articular injection once a week for a total of 3 consecutive injections, with either SH 20 mg/2.0 ml (Ostenil®, TRB Chemedica AG, Germany) or lidocaine hydrochloride 20 mg/2.0 ml. The WOMAC index and consumption of the rescue medication (ibuprofen 200 mg tablets) were measured at Weeks 4, 12 and 24 in the double-blind portion of the study in both groups and at Week 48 in the SH group.

Results: 39 patients in the SH group and 29 in the lidocaine group were analysed. Five patients in the lidocaine group prematurely discontinued the study due to lack of efficacy. Both groups' characteristics were homogeneous at baseline. Pain and total WOMAC decreased significantly in the SH group compared to the lidocaine group up to Week 24 (ANOVA $p < 0.002$ and $p < 0.042$, respectively). The SH group demonstrated a statistically significant decrease in pain and disability at Week 48 ($p < 0.0001$). These effects were associated with a statistically significant reduction of the average daily ibuprofen dose ($p < 0.009$). No local or systemic undesirable effects were reported during the study.

Conclusion: The results show the capacity of SH to reduce pain and improve functional activity of patients with hip OA during 12 months.

Disclosure of Interest: None declared

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