Medical or Research Professionals/Clinicians

Topic area: Clinical topics by disease

Specific topic: 23. Osteoarthritis

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MULTICENTRIC OSTEOARTHRITIS INTERVENTION STUDY WITH SYSADOA (MOVES): EFFECTS OF COMBINED GLUCOSAMINE HYDROCHLORIDE AND CHONDROITIN SULFATE VS CELECOXIB FOR PAINFUL KNEE OSTEOARTHRITIS

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My abstract has been or will be presented at a scientific meeting during a 12 months period prior to EULAR 2014: Yes

Abstract presented or will be presented at (meeting): OARSI, SER, ACR, SEMERGEN, SEC, semFYC

Is the first author applying for a travel bursary?: No

Background: Combined glucosamine hydrochloride (GH) and chondroitin sulfate (CS) was found to be efficacious compared with placebo in subjects with knee osteoarthritis (OA) with severe pain in the GAIT trial[1]. The proportion of OA patients who achieved after 6 months a 20% improvement in pain was similar between GH+CS and Celecoxib (CE) 200mg.

Objectives: To extend the findings of GAIT, a non-inferiority clinical trial was designed to assess whether GH+CS has comparable efficacy to CE to reduce severe pain in knee OA patients after 6 months of treatment. Secondary objectives included comparison of other outcomes related to signs and symptoms of knee OA and to tolerability and safety.

Methods: MOVES was an international multicentric, phase IV, double-blind, non-inferiority, randomized trial to compare efficacy and safety of combined GH+CS (Droglican®, Bioiberica) *vs* CE in patients with knee OA with severe pain. Patients received either 2 capsules of Droglican (GH 250mg and CS 200mg) TID or CE 200mg and 5 placebo capsules. Patients were eligible if ≥40years, fulfilled the ACR criteria for knee OA, had KL grade 2 or 3 and WOMAC pain>301 (0-500scale). Patients with gastrointestinal or cardiovascular risk were excluded. The primary outcome was the mean decrease in WOMAC Pain after 6 months.

Results: 763 patients were screened, 606 randomized to receive GH+CS (N=304) or CE (N=302), 522(86.1%) completed the trial and included in the PP non-inferiority analysis. There was no difference in proportion completing between groups. Mean(SD) age was 62.7(8.9) years, 438(83.9%) were women; KL grade 2 was present in 327(62.6%).

The mean WOMAC pain at randomization was 372.0(41.8) in GH+CS and 370.6(41.4) in CE. At 6 months, pain decreased ~50% in both groups to 185.8(7.4) in GH+CS and 184.7(7.6) in CE, SEM difference of 1.11(10.63) units (95%CI-21.99,19.76) (p=0.917) respecting non-inferiority margin. These results were robust in sensitivity analyses using the ITT population and BOCF imputation in PP and ITT populations.

There was no difference in secondary outcomes after the 6-month treatment with WOMAC stiffness of 69.1(3.0) and 65.8(3.0) (p=0.434), WOMAC function of 617.0(23.5) and 595.8(24.1) (p=0.53), VAS pain of 37.9 and 37.6 (p=0.924) and OMERACT-OARSI responders of 79.7% and 79.2% (p=0.908) in GH+CS and CE groups respectively. Both arms elicited a reduction>50% in joint swelling (p= 0.53) and effusion (p= 0.61). Overall, there was similar rescue medication consumption in both arms. There was no significant difference in the proportion of patients with treatment-emergent AEs between groups (50.7% overall); no deaths occurred.

All the results are consistent with those from the GAIT.

Conclusions: The MOVES demonstrated clinical efficacy of a combination of GH and CS and good safety profile in the symptomatic treatment of patients with severe knee OA.

References: [1] N Engl J Med 2006 Feb 23;354(8):795-808

Disclosure of Interest: None declared