[2002] [THU0196] GLUCOSAMINE SULFATE SLOWS-DOWN OSTEOARTHRITIS PROGRESSION IN POSTMENOPAUSAL WOMEN: POOLED ANALYSIS OF TWO LARGE, INDEPENDENT, RANDOMISED, PLACEBO-CONTROLLED, DOUBLE-BLIND, PROSPECTIVE 3-YEAR TRIALS

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Background: Osteoarthritis (OA) is an age and sex-related, chronic, frequent, disabling and resources consuming disease, typically affecting women in the post-menopausal (PM) period. PM women might be the pool of patients looking most frequently for OA advise. In spite of the currently available therapy armamentarium, the long-term effective control of OA symptoms, disability and structural progression unmet medical need. Current clinical evidence suggests that glucosamine sulfate might be postulated as an OA Modifying Drug. We conducted two studies to independently test the long-term effects of the drug on the progression of knee-OA joint structural changes and symptoms over a long-term period of 3 years in the general OA population. 77% of the two studies population was PM women.

Objectives: To demonstrate that Glucosamine sulfate slows down the disease progression in the PM sub-population of the two studies.

Methods: 319 of the 414 randomised patients were female with knee-OA (ACR criteria). 311 of them were PM (> 1 year of amenhorrea). Patients were randomly assigned to continuous treatment with oral glucosamine sulfate 1500 mg once-a-day for 3 years or placebo. Weight-bearing, antero-posterior radiographs of each knee were taken at enrolment and at yearly intervals standardising patient positioning and radiographic procedure. Joint space width (JSW) at the narrowest point was measured visually by a 0.1 mm graduated magnifying glass, according to a validated technique. Symptoms were scored by the WOMAC index and, in one of the studies, also by the Lequesne index.

Results: In the two studies, the groups were comparable for demographic and disease characteristics. The PM sub-population mean age was 66 and 62 in the first and second study, respectively. After 3 years PM population showed no JSN in the glucosamine sulfate group, while placebo patients had minimum joint space narrowing (JSN) of 0.33 mm ($p < 0.0001$), in the intention-to-treat population, as shown in table I. The per-protocol results were also statistically in favour of Glucosamine sulfate. Symptoms significantly improved in the glucosamine sulfate group. In the first study, the WOMAC index improved by -14.1% in the glucosamine group vs. a worsening of 14.2% in the placebo group ($p=0.008$). In the second study, the Lequesne index improved by -19.3% in the active group and only by -6.9% in the control group ($p=0.003$). In the second study, the WOMAC index also improved significantly in the glucosamine group.

	Placebo (n=157)	Glucosamine sulfate (n=154)	Difference (95% CI)	p
3-years. Joint space narrowing (mm) Ave (95% CI)	-0.33 (-0.45 to -0.24)	0.002 (-0.04 to 0.9)	0.33 (0.18 to 0.48)	<0.0001

Conclusion: These two independent, long-term studies demonstrated for the first time that a pharmacological intervention may induce a Disease Modifying effect in Osteoarthritis in the PM population, the most frequently affected by Osteoarthritis.

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