



ARTHRITIS & RHEUMATISM

Effects of Glucosamine Sulfate on 6-Month Control of Knee Osteoarthritis Symptoms vs. Placebo and Acetaminophen: Results from the Glucosamine unum In Die Efficacy (GUIDE) Trial

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PURPOSE

Two multicenter, randomised, placebo-controlled, double-blind trials have been lately investigating the efficacy of oral glucosamine in knee osteoarthritis (OA), using a symptomatic medication as reference: GAIT performed by the NIH in the US with nutraceutical glucosamine hydrochloride 500 mg t.i.d. vs celecoxib, and GUIDE performed in Europe with the original prescription glucosamine sulfate 1500 mg once-a-day (u.i.d.) vs acetaminophen, i.e. the preferred symptomatic medication in OA practice guidelines. We report the results of GUIDE.

METHODS

318 patients (88% women) with knee OA (ACR criteria) were randomised to double-dummy oral glucosamine sulfate soluble powder 1500 mg u.i.d., or acetaminophen 1000 mg tablets t.i.d. (3 g/day, as recommended in Europe), or placebo, for 6 months. The rescue medication consisted of standardised use of ibuprofen 400 mg tablets (daily diary recording). The primary efficacy parameter was the 6-month change in the Lequesne index in the ITT population, using the LOCF approach for patients not completing the study according to the protocol (34 on placebo, 28 in each the acetaminophen and glucosamine sulfate groups, without differences in drop-out reasons). Secondary efficacy parameters included the changes in the WOMAC index and the OARSI-A responder criteria. Statistical analysis on the indexes was performed by GLM-ANOVA, with Dunnett's pairwise comparisons vs placebo. The proportions of responders and patients using the rescue medication were compared by the chi-square test.

RESULTS

The groups were comparable for demographics and baseline disease characteristics. Glucosamine sulfate efficacy vs placebo was significant on all parameters (table). Acetaminophen had more responders than placebo, but it failed to reach a significant difference on the Lequesne (p=0.18) and WOMAC (p=0.077) indexes. More patients on placebo used the rescue medication (p=0.027 and 0.045 vs glucosamine sulfate and acetaminophen, respectively). There were no differences among groups in safety.

CONCLUSIONS

Glucosamine sulfate at the oral once-daily dose of 1500 mg might be the preferred symptomatic medication in knee OA.

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Baseline Lequesne and WOMAC, with 6-month ITT changes and % of OARSI-A responders

	Placebo (N= 104)		Acetaminophen (N=108)		Glucosamine sulfate (N=106)	
	Baseline	6 months	Baseline	6 months	Baseline	6 months
Lequesne (points) ^a	10.8 (2.6)	-1.9 (-2.6 to -1.2)	11.1 (2.7)	-2.7 (-3.3 to -2.1)	11.0 (3.1)	-3.1 [†] (-3.8 to -2.3)
WOMAC (points) ^a	37.9 (14.3)	-8.2 (-11.3 to -5.1)	40.4 (14.8)	-12.3 (-14.9 to -9.7)	38.3 (15.2)	-12.9 [†] (-15.6 to -10.1)

OARSI-A responders (%)

	-	21.2%	-	33.3% [‡]	-	39.6% [§]
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^a Mean absolute (SD) at baseline and change (95%CI) at 6 months.
[†] P vs placebo: [†]0.032 [difference = -1.2 (-2.3 to -0.8)]; [‡]0.039 [difference = -4.7 (-9.1 to -0.2)]; [§]0.047; [§]0.007

