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Prospective, multi-centre, randomised evaluation of the safety and efficacy of five dosing regimens of viscosupplementation with hylan G-F 20 in patients with symptomatic tibio-femoral osteoarthritis: a pilot study.

Conrozier T, Jerosch J, Beks P, Kemper F, Euller-Ziegler L, Bailleul F, Chevalier X
Department of Rheumatology, Centre Hospitalier Lyon Sud, Pierre Bénite, France, thierry.conrozier@chu-lyon.fr

INTRODUCTION: Viscosupplementation by repeated intra-articular injections of hyaluronic acid (HA) is used widely in the treatment of symptomatic knee osteoarthritis (OA). The number of injections required can limit the availability of treatment and affect patient compliance. The aim of this study was to assess different dosing regimens of hylan G-F 20, a high molecular-weight cross-linked derivative of HA, in the treatment of pain due to knee OA.

MATERIALS AND METHODS: Pilot, prospective, multi-centre, open-label, randomised trial in 100 patients with unilateral, symptomatic, tibio-femoral OA (Kellgren-Lawrence grade II or III), aged >/=40 years. Patients were randomised to receive varying dosing regimens of hylan G-F 20 (1 x 6 mL, 1 x 4 mL, 2 x 4 mL 2 weeks apart, 3 x 4 mL 1 week apart, or 3 x 2 mL 1 week apart). Adverse events (AE's) were monitored throughout the study. The primary efficacy endpoint was the change from baseline in the patient-rated knee OA pain assessment (100 mm visual analogue scale (VAS)) at 24 weeks. The secondary efficacy criteria included the WOMAC index, patient and physician global assessments using a 100 mm VAS, and knee OA pain assessment at all other visits. Concomitant use of permitted rescue medications (paracetamol) was also assessed.

RESULTS: The treatment was well tolerated overall. Patients in the 3 x 4 mL group reported the highest percentage of device-related local AE's (30%) while patients in the 1 x 6 mL and 3 x 2 mL groups reported only 10%. There were no serious device-related AEs. There was a statistically significant improvement from baseline at week 24 in all efficacy endpoints for all treatment regimens. The 1 x 6 and 3 x 4 and 3 x 2 mL treatment groups showed the greatest mean improvements (-34.9, -32.6 and -36.7 mm respectively) in the patient-rated knee OA pain assessment VAS.

CONCLUSION: This study suggests that a single 6 mL injection of hylan G-F 20 may be as efficacious, and as well tolerated, as 3 x 2 mL one week apart. A double-blind, controlled trial is needed to confirm these data.

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