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Intra-articular hyaluronan (Synvisc®, hylan G-F 20) for the treatment of first metatarsophalangeal joint osteoarthritis: a randomised, placebo controlled trial

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Background

The objective of this randomised controlled trial (RCT) was to comparatively assess the effectiveness of intra-articular hyaluronan (Synvisc®, hylan G-F 20) against an intra-articular sterile saline placebo for the treatment of radiographically confirmed, symptomatic first metatarsophalangeal joint (MTPJ) osteoarthritis (OA).

Methods

One hundred and fifty one (n=151) participants with symptomatic first MTPJ OA were randomly allocated to receive up to 1ml intra-articular injection of either Synvisc®, hylan G-F 20 or a sterile saline placebo. Outcomes were evaluated at 1, 3 and 6 months post-injection. Primary outcome measurements included the *foot pain* and *foot function* sub-scales of the Foot Health Status Questionnaire (FHSQ). Secondary outcome measurements were pain at the first MTPJ during walking and rest, self-reported stiffness at the first MTPJ, magnitude of symptom change with allocated treatment, global satisfaction, health-related quality of life (assessed via the Short-Form-36, version two), first MTPJ dorsiflexion range of motion, strength of the hallux plantarflexors, use of pain-relieving medication, concomitant therapies and dynamic plantar pressures.

Results

This RCT was completed in July 2010, with 147 (97%) participants followed up at 1 month, 127 (84%) at 3 months and 135 (89%) at 6 months. Both the placebo and treatment groups displayed improvements at the 1, 3, and 6 month follow-up periods. However, there were no statistically significant differences between the placebo or treatment groups for the primary outcome measures of FHSQ *foot pain* and *footfunction* during any review period. With few exceptions, there were no statistically significant differences in the secondary outcome measurements between the groups.

Conclusions

A single intra-articular injection of Synvisc®, hylan G-F 20 is no more effective than a single intra-articular injection of sterile saline (placebo) in reducing symptoms and improving function in people with symptomatic, radiographically confirmed first MTPJ OA.

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