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Effectiviness Of Hyaluronic Acid For Mild To Modate Osteoarthritis Of The Knee. A Randomized Clinical Trial Of Fermathron Plus Versus Placebo

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Introduction: Background: Controversy exists around the clinical effectiveness of hyaluronic acid (HA), in use since the 90's of last century. After measuring positive outcomes on knee pain and treatment satisfaction in a consecutive cohort of patients with osteoarthritis (OA) of the knee in our clinic, we conducted a large randomized clinical trial.

Objectives: Our main study question was: are three intra-articular injections with HA more effective for knee pain and function than a placebo treatment?

Methods: A double blind, randomized clinical trial (RCT) in which patients with mild to moderate OA of the knee received either three intra-articular injections with HA (Fermathron plus tm, Hyaltech, Edingburgh, Scotland) or three injections with placebo. The study was conducted in two hospitals. Knee OA was confirmed on a standard antero-posterior knee radiograph and scored using the Kellgren and Lawrence (KL) classification. Patients with a KL score 1 to 3 were included and patients with previous HA treatment were excluded. Subgroup analyses on pre-treatment duration of symptoms, pain severity or radiological OA severity were planned. A priori a power analysis was calculated and we included 200 patients. Injections were weekly with follow-up at 1, 3 and 6 months which included VAS scores for pain, WOMAC scores, knee range of motion, treatment satisfaction and adverse events. Results were analysed before blinding of both groups was broken. Ethical Review Board approval was received before the first patient was included.

Results: Baseline details (i.e. age, knee OA severity, pain scores etc.) were comparable between groups. Four patients were lost to follow-up. Although pain scores improved significantly from baseline, there were no significant differences observed between both groups. All other outcome measurements (treatment satisfaction, general knee score (VAS), WOMAC, knee range of motion) were also comparable between groups, at all follow-up time intervals.There were no significant differences between subgroups based on pre-treatment pain severity, duration of symptoms or knee OA severity. There were no (serious) adverse events during the study.

Conclusions: Only one previous study using this particular HA was published, in which a comparison with another HA product was made and improvement from baseline was observed. Previous systematic reviews on the effectiveness of HA treatment present inconclusive results, indicating treatment results being dependent on specific HA product details such as molecular weight. Our RCT results show that the treatment effect of three weekly injections of HA using Fermathron plus, (2ml injections, 30mg HA with a molecular weight of 2.2M Dalton) is not superior to placebo. We cannot recommend the use of three injections of this particular HA product for patients with mild to moderate knee OA.