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POLYACRYLAMIDE HYDROGEL FOR KNEE OSTEOARTHRITIS: 5-YEAR RESULTS FROM A PROSPECTIVE STUDY
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**Introduction** Polyacrylamide hydrogel (iPAAG), is CE marked for treating symptomatic knee osteoarthritis (OA), meeting the need for an effective, long-lasting, and safe non-surgical option. This study evaluates the efficacy and safety of a single 6 ml intra-articular injection of iPAAG in participants with moderate to severe knee OA over a 5-year post-treatment period.

**Methodology** This prospective multicentre study (3 sites in Denmark) involved 49 participants (31 females) with an average age of 70 (range 44 – 86 years). They received a single 6 mL iPAAG injection. All participants provided informed consent and re-consented to continue after 1 year. The study followed GCP principles and was approved by Danish health authorities and local Health Research Ethics committees. One of the sites closed after the first year, while twenty-seven participants from the other sites completed the 5-year follow-up. The study evaluated WOMAC pain, stiffness, function, and Patient Global Assessment (PGA) of disease impact. Changes from baseline were analysed using a mixed model for repeated measurement (MMRM). Sensitivity analyses were applied on the extension data, where the MMRM analysis was repeated only including patients in the extension phase and an ANCOVA model was used, replacing missing values at 5-years with baseline values (BOCF).

**Results** The originally planned MMRM analysis including all available data from the 49 treated participants showed a statistically significant decrease in WOMAC pain scores (-14.6; 95% CI: -21.4; -7.7) from baseline to 5 years. The analysis only using data from the extension phase participants (n=27) showed similar results (-15.6; 95% CI: -22.3; -8.9). The BOCF analysis also showed a clinically relevant and statistically significant decrease in the WOMAC pain subscale from baseline (-9.1 units). Seven new adverse events were reported between the 4-year and 5-year visits, with two reported as serious (acute myocardial infarction and femoral neck fracture). None of these seven events were related to the treatment.

**Conclusions** This study shows that single injections of 6 ml intra-articular iPAAG were well tolerated and continued to provide clinically important effectiveness at 5-years after treatment. Acknowledgements The study was sponsored by Contura International A/S