SAFETY, TOLERABILITY AND PRELIMINARY OUTCOME OF PERCUTANEOUSLY INJECTED CHONDROGEN™, A PROPRIETARY CULTURE-EXPANDED WHARTON'S JELLY DERIVED-MESENCHYMAL STEM CELLS IN PATIENTS WITH KNEE OSTEOARTHRITIS

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Introduction: This study evaluates the effect of Wharton-Jelly derived mesenchymal stem cell for patients with knee osteoarthritis, primarily the safety profile, followed by the clinical and radiological outcomes.

Methodology: This Phase 1, Open-Label, Single-Arm Trial has selected a total of eleven patients with Kellgren-Lawrence Grade 2 and 3. All of them received the CHONDROGENTM injection which contains 15 x 106 mesenchymal stem cells. These patients were followed up at 2 weeks, 6 weeks, 12 weeks and 24 weeks. The following parameters were assessed at each follow up: Adverse Events, Number of Analgesia, Visual Analogue Scale (VAS) 100mm, Sit-to-Stand Test, IKDC Subjective Knee Evaluation, KOOS Score, Tegner Activity Scale and Lysholm Knee Score. A plain radiograph of the knee was taken before the injection and repeated after 24 weeks. Statistical analysis was done using ANOVA and Kruskal-Wallis analysis with SPSS.

Discussion: There were no serious adverse events, deaths, permanent disability or hospitalization reported. The commonest adverse event observed was transient knee pain and swelling, which resolved spontaneously within 72 hours. Reduction of the Number of Analgesia was seen as early as 2 weeks. There is an improvement of VAS 100mm up to 27% (72.2mm Â± 20.0mm to 19.5mm Â± 18.7mm, p=.00) (Figure 1). The number of repetitions in the Sit-to-Stand Test also almost doubled (11.4reps Â± 4.8reps to 21.0reps Â±6.5reps, p=.00). Similar improvements were also seen with IKDC Subjective Knee Score, KOOS Score and Lysholm Knee Score. There was no significant change seen with neither the Tegner Activity Scale nor the radiological assessment.

Conclusion: Wharton-Jelly derived mesenchymal stem cell knee injection has been demonstrated to be safe in a short term study.