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Mesoblast NeoFuse shows +ve results

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Singapore: Regenerative medicine company Mesoblast's phase II clinical trial for lumbar spinal fusion successfully met its safety and efficacy endpoints. The results suggest that Mesoblast's NeoFuse product comprising allogeneic Mesenchymal Precursor Cells (MPCs) is as effective for interbody lumbar fusion as the gold standard, bone autograft, without the need for a second surgical procedure and its attendant morbidity risks.

Around 24 patients were enrolled and randomized over five sites in the US with eight patients in each treatment arm, bone autograft standard of care (Control), 25 million MPCs (25M), and 75 million MPCs (75M). Patients underwent the surgical procedure, one-or-two level fusions using a posterior approach to the spine, and were evaluated for safety and efficacy. The median follow-up times for the three treatment groups were 23.9, 20.7, and 22.9 months for the bone autograft, 25M, and 75M groups, respectively.

MPCs were well tolerated with no cell-related serious adverse events and no ectopic bone formation at all. Notably, MPC treated groups had 30-to-43 percent lower mean estimated blood loss during surgery compared to the autograft treatment group ($p < 0.05$ for the 25M group). At 12 months, fusion was achieved in 85.7 percent of patients in the 25M treatment group compared to 62.5 percent in the 75M and 75 percent in the control patient groups.

Overall, patients from all three treatment groups had a clinically significant and comparable decrease in low back and leg pain, assessed on the Visual Analogue Scale and functional improvement, assessed by the Oswestry Disability Index questionnaire.

Mesoblast plans to initiate a phase III trial for interbody lumbar fusion later this year, with patients to be enrolled across multiple sites in the US, Europe and Australia.