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Repeated injection of autologous mesenchymal stem cells in patients with knee osteoarthritis: Randomized double blind clinical trial Royan Institute (RIMRO-Trial)

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Background: Osteoarthritis (OA) is a degenerative joint disorder and is a common condition in elderly. Recent non-randomized studies including our three previous phase I/II clinical trials have shown the safety of mesenchymal stem cells injection in the treatment of osteoarthritis.

Study objects and design: To investigate the effects of intra articular injection of autologous bone marrow derived mesenchymal stem cells (BM-MSC) on the symptoms of moderate to severe knee osteoarthritis we performed a double blind, placebo-controlled study in 46 patients. Eligible patients were 18 to 65 years old and had a joint pain visual analog scale of >30 mm (at rest). Patients fulfill criteria for knee OA were randomly assigned into two groups: Group one received BM-MSC (20 million cells, twice at day 0 and week 12th) and group two received carrier media as placebo. Primary end points were the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and a visual analogue score (VAS) for pain at baseline and at the end of weeks 12, and 24, 36. Secondary end points were pain free walking distance and WOMAC stiffness sub score and cartilage thickness, subchondral edema, tumor formation or neoplastic changes at 24 and 36 weeks.

Results: The results indicated that the intra articular injection of autologous BM-MSC is very well tolerated during the 9 months trial. Moreover BM-MSC treated group had significantly clinical improvement as compare to placebo group in all clinical end points. In particular, the WOMAC-Total score, WOMAC-Physical Function sub score, WOMAC-pain sub score and pain free walking distance in BM-MSC, were superior compared to the placebo group ($P=0.03$, $p=0.02$, $p=0.03$ and $P=0.01$, respectively). Other clinical endpoints including the WOMAC-Stiffness, and VAS scores were also improved in both groups as compared to the baseline; but no statistical significance was detectable between two groups. Primary radiologic data indicated that subchondral edema decreased in some patients also thickness of cartilage increased in MSC group. Evaluation of radiographic data is not complete yet.

Conclusion: Our short term follow up (9 months) have shown that repeated intra articular injection of BM-MSC is safe and effective in reducing functional impairment and relieving pain in patients with moderate to severe osteoarthritis of the knee.

Biography

Nasser Aghdami earned his MD degree from the Urumieh Medical University (1998), and PhD in Immunology from Tarbiat Modares University (2004) in Iran. During (2000- 2006) he was an Associate Investigator at Hematology and Oncology in Royan Institute and his research focused on Stem Cell Biology. He has published over 40 international papers and editorial boards related to Stem Cell, Clinical Trail, and Cell therapy. He is the editor of three books in Stem Cell and Regenerative Medical field. He was prestigious award from his research include young investigator in 2012.

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