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A Prospective, Single-Blind, Placebo-Controlled Trial of Bone Marrow Aspirate Concentrate for Knee Osteoarthritis.

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Abstract

BACKGROUND: Bone marrow aspirate concentrate (BMAC) is increasingly used as a regenerative therapy for musculoskeletal pathological conditions despite limited evidence-based support.

HYPOTHESIS: BMAC will prove feasible, safe, and efficacious for the treatment of pain due to mild to moderate degenerative joint disease of the knee.

STUDY DESIGN: Randomized controlled trial; Level of evidence, 2.

METHODS: In this prospective, single-blind, placebo-controlled trial, 25 patients with bilateral knee pain from bilateral osteoarthritis were randomized to receive BMAC into one knee and saline placebo into the other. Fifty-two milliliters of bone marrow was aspirated from the iliac crests and concentrated in an automated centrifuge. The resulting BMAC was combined with platelet-poor plasma for an injection into the arthritic knee and was compared with a saline injection into the contralateral knee, thereby utilizing each patient as his or her own control. Safety outcomes, pain relief, and function as measured by Osteoarthritis Research Society International (OARSI) measures and the visual analog scale (VAS) score were tracked initially at 1 week, 3 months, and 6 months after the procedure.

RESULTS: There were no serious adverse events from the BMAC procedure. OARSI Intermittent and Constant Osteoarthritis Pain and VAS pain scores in both knees decreased significantly from baseline at 1 week, 3 months, and 6 months ($P \leq .019$ for all). Pain relief, although dramatic, did not differ significantly between treated knees ($P > .09$ for all).

CONCLUSION: Early results show that BMAC is safe to use and is a reliable and viable cellular product. Study patients experienced a similar relief of pain in both BMAC- and saline-treated arthritic knees. Further study is required to determine the mechanisms of action, duration of efficacy, optimal frequency of treatments, and regenerative potential. Registration: ClinicalTrials.gov record 12-004459.