

Phase 3 Pivotal Trial Comparing CARTISTEM® and Surgical Comparator for Knee Cartilage Lesions and Osteoarthritis

NCT07339111

Status	RECRUITING
Phase	Phase 3
Sponsor	Medipost, Inc.
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (25)

- Age e 18 and d 75 years old.
- Knee Osteoarthritis diagnosed in the index knee according to the clinical definition of American College of Rheumatology (ACR) guidelines at screening.
- Failed conservative knee osteoarthritis treatment for at least 3 months prior to consent (weight reduction, physical therapy, injections, pain medications, etc.).
- Kellgren-Lawrence (KL) in the index knee of grade 2 to 3 as determined by independent radiologist review of study X-Ray.
- Clinically relevant femoral cartilage defects classified using modified Outerbridge Grade 3 or 4 in index knee with combined lesion area e 2 cm² and d 9 cm² and at least a single femoral lesion e 2 cm² as determined by independent radiologist review of study MRI.

... and 20 more (see full listing online)

Exclusion (35)

- Subject received an IA injection of Hyaluronic Acid (HA), Platelet Rich Plasma (PRP), Bone Marrow Aspirate / Concentrate (BMA / BMAC), long-acting / conventional steroid, or investigational drug in either knee within 3 months of signing informed consent. Note: injections of the contralateral knee are allowed during the trial.
- Bone marrow lesion (BML) grade 3 on femur, tibia, or patella except at femoral lesion area (BML grade 3 allowed) in index knee as determined by independent radiologist review of study MRI.
- KL index knee grade 0, 1 or 4 as determined by independent radiologist review of study X-Ray.
- KL Contralateral knee severity grade 4 as determined by independent radiologist review of study X-Ray.
- Anatomical axis varus or valgus malalignment e 6° in either knee as determined by independent radiologist.

... and 30 more (see full listing online)

Locations (13 total)

Flourish Research Birmingham, Birmingham, Alabama, United States
AZ Orthopedic, Tempe, Arizona, United States
TriWest Research Associates, El Cajon, California, United States
... and 10 more locations

<https://clinicaltrials.gov/study/NCT07339111>

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