A Study of MACI in Patients Aged 17 to 65 Years With Symptomatic Chondral or Osteochondral Defects of the Ankle

NCT06915233

Status	RECRUITING
Phase	Phase 3
Sponsor	Vericel Corporation
Enrollment	309 participants

Key Eligibility Criteria

Inclusion (8)

- Age 17 to 65 at the time of planned randomization visit (Visit 2).
- One or more symptomatic chondral or osteochondral lesion/s as defined by FAOS Pain score d 50 and FAOS Function (SRA) score d 50.
- International Cartilage Repair Society (ICRS) Score Grade 3 or 4 chondral or osteochondral lesion/s located on the talus with or without cysts, including shoulder lesions (lesions on the talar neck), and amenable to treatment with the surgical procedure specified at randomization.
- At least 1 lesion e 1.2 cm².
- Written informed consent and assent (as applicable) per Institutional Review Board (IRB) requirements.

... and 3 more (see full listing online)

Exclusion (20)

- Lesions with an underlying bony defect depth of \> 5 mm.
- Any surgery on the target joint within 24 weeks prior to Visit 1 (not including diagnostic ankle arthroscopy).
- Previous investigational drug, biologic or device use within 12 weeks prior to Visit.
- Avascular necrosis of the target ankle.
- Symptomatic musculoskeletal conditions in the lower limbs that could impede measurement of efficacy for the target ankle joint.

... and 15 more (see full listing online)

Locations (4 total)

MedStar Georgetown University Hospital, Washington D.C., District of Columbia, United States
NextStage Clinical Research Wichita - Kansas Joint and Spine specialists, Wichita, Kansas, United States
NextStage Clinical Research Houston - All American Orthopedic and Sports Medicine, Houston, Texas, United States
... and 1 more locations