

# A Study of MACI in Patients Aged 10 to 17 Years With Symptomatic Chondral or Osteochondral Defects of the Knee

NCT03588975

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Status	RECRUITING
Phase	Phase 3
Sponsor	Vericel Corporation
Enrollment	45 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Symptomatic cartilage or osteochondral defects
- One or more International Cartilage Repair Society (ICRS) Grade III or IV chondral or unsalvageable osteochondral defects located on the femoral condyles and/or trochlea amenable to treatment with the surgical procedure determined at randomization (MACI or microfracture).
- At least 1 defect size  $\geq 1.5$  cm<sup>2</sup> on the femoral condyles and/or the trochlea; defects include OCD lesions with a bone lesion depth of  $\geq 6$  mm and does not require a bone graft.
- Stable target knee (i.e., anterior and posterior cruciate ligaments should be free of laxity as well as stable and intact). Ligament repair or reconstruction procedures are allowed prior to screening arthroscopy.
- Intact meniscus or partial meniscus (at least 50% of functional meniscus remaining) in the target knee.

### Exclusion (6)

- Any surgery on the target knee joint within 6 months prior to Screening (not including diagnostic arthroscopy)
- ICRS Grade III or IV chondral or unsalvageable osteochondral defects located on the patella or tibia or any lesion that is bipolar to the index lesion
- Concomitant inflammatory disease or other conditions that affects the joints (eg, rheumatoid arthritis, metabolic bone disease, psoriasis, symptomatic chondrocalcinosis)
- Known history of septic arthritis in the index knee joint
- Known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin
- ... and 1 more (see full listing online)

## Locations (12 total)

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Stanford University, Palo Alto, California, United States  
Shriner's Hospital for Children Northern California, Sacramento, California, United States  
University of California Davis Health, Sacramento, California, United States  
... and 9 more locations

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<https://clinicaltrials.gov/study/NCT03588975>

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