

# Safety and Tolerability of IMM01-STEM in Patients With Muscle Atrophy Related to Knee Osteoarthritis.

NCT05211986

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Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Immunis, Inc.
Enrollment	28 participants

## Key Eligibility Criteria

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### Inclusion (16)

- Has moderate KOA (defined as Kellgren-Lawrence \[KL\] grade 2 to 3) on affected limb
- Has quadriceps weakness ( $<7.5\text{N/kg}$ )
- Can ambulate  $>50$  feet unassisted
- This criteria deleted with protocol amendment 6
- Has a body mass index (BMI) of  $<40\text{kg/m}^2$

... and 11 more (see full listing online)

### Exclusion (18)

- Severe KOA (defined as KL grade  $>3$ ) on contralateral limb
- Has had prior total knee arthroplasty
- Has a known hypersensitivity to any components of the study medication or comparative drugs (and/or an investigational device) as stated in this protocol
- Has current or past history of malignancy (5y) excluding nonmelanoma skin cancer
- Has neurological, vascular, or cardiac condition that limit function, or, in the opinion of the investigator, could jeopardize or would compromise the study participant's ability to participate in this study

... and 13 more (see full listing online)

## Locations (2 total)

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Orthopaedic Specialty Institute, Irvine, California, United States  
University of California, Irvine - Alpha Stem Cell Clinic, Orange, California, United States