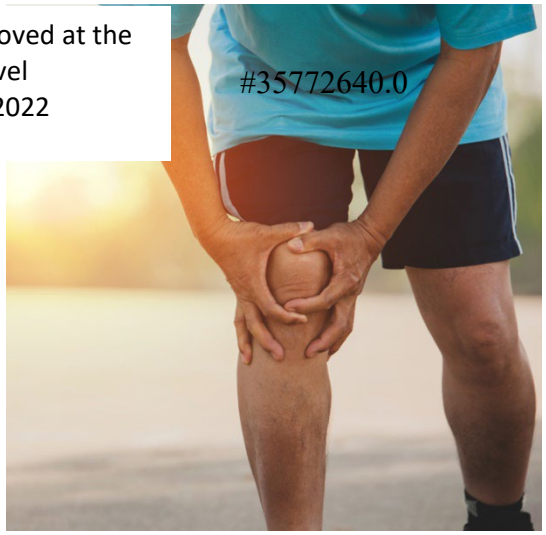
IRB Approved at the
Study Level
Nov 02, 2022
#35772640.0

Immunis, Inc. STEM-MYO Knee Osteoarthritis Clinical Trial



University of California, Irvine | UCLA-UCI Alpha Stem Cell Clinic

Study Title: An Open-Label Dose Escalation Study To Assess The Safety And Tolerability Of IMM01-STEM In Participants With Muscle Atrophy Related To Knee Osteoarthritis

Lead Investigator: Dean Wang, MD
Study Sponsor: Immunis, Inc.

What is the study?

The purpose of this research is to study the effects of IMM01-STEM in humans and assess the safety and tolerability in participants who have muscle atrophy or weakness due to knee osteoarthritis.

How can I take part in this trial?

Please note this may not be a complete list of eligibility criteria.

Main Inclusion Criteria

- Adults 50-75 years of age
- Confirmed mild to moderate osteoarthritis in one knee.
- Willing and able to comply with all study requirements

Main Exclusion Criteria

- Prior knee replacement surgery
- Moderate or severe osteoarthritis in the opposite knee
- History of cancer within the last 10 years, except for some skin cancers
- Current or past history of smoking within last 10 years

How does it work?

IMM01- STEM is an injectable solution composed of proteins that were created by stem cells. It has been shown to increase muscle mass and strength in animal studies. This is the first time IMM01-STEM is being studied in humans.

How long will my participation last?

Study participation will last approximately 20 weeks from screening to the safety follow-up period.

The treatment period lasts 4 weeks and requires two visits per week where participants will receive IMM01-STEM injections into the thigh muscle of the affected side. Participants will be observed for 30 minutes before and 3 hours after each injection to monitor for injection related reactions and other adverse events. A 3 month Safety Follow Up period will begin after the final treatment and consist of monthly follow up visits. Between 9-18 subjects will participate in this research.

Will I be compensated?

Participants will be compensated for portions of the study requirements.

For more information, please contact:

UC Irvine Alpha Stem Cell Clinic
(714) 456-5956 or stemcell@uci.edu

Additional study information available at ClinicalTrials.gov by using the QR code

SCAN ME