

A Trial to Investigate the Safety and Efficacy of Intra-articular 4P004 Injection in Subjects With Knee Synovitis and Osteoarthritis

NCT07225829

Status	RECRUITING
Phase	Phase 2
Sponsor	4Moving Biotech
Enrollment	129 participants

Key Eligibility Criteria

Inclusion (17)

- Participants who have the capacity to give informed consent and who are willing to comply with all trial related procedures and assessments.
 - Participants between 40 and 80 years of age.
 - Female participant of childbearing potential (defined as any woman unless postmenopausal for at least one year or surgically sterile) must use highly effective methods of contraception as defined in the protocol. Highly effective contraceptive measures must be continued throughout the trial until the final visit.
 - Bodyweight \geq 40 kg.
 - Body mass index (BMI) \geq 18.5 and \leq 35.
- ... and 12 more (see full listing online)

Exclusion (31)

- Pregnant or breastfeeding women.
 - Significant malalignment of anatomical axis (medial angle formed by the femur and tibia) of the TK (varus \geq 10°, valgus \geq 10°) by radiography.
 - Secondary OA such as joint dysplasia, aseptic osteonecrosis, joint infection, acromegaly, Paget disease, hemochromatosis, joint crystal disease or any inflammatory joint disease.
 - Any known active infections including skin infections at the site injection or increased predisposition for the development of infections.
 - Any partial knee replacement of the TK.
- ... and 26 more (see full listing online)

Locations (21 total)

Northwestern University Feinberg School of Medicine, Chicago, Illinois, United States
Skylight Health Research Burlington, Burlington, Massachusetts, United States
Durham Bone and Joint Specialists, Ajax, Canada
... and 18 more locations