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Efficacy of bone marrow concentrate injection in the treatment of knee osteoarthritis in the elderly

Submission date
24/11/2025

Recruitment status
Recruiting

Registration date
25/11/2025

Overall study status
Ongoing

Last Edited
28/11/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Study information

Scientific Title
Efficacy of intra-articular injection of bone marrow concentrate in the treatment of knee osteoarthritis in elderly patients

Study objectives
Main objective: To assess the efficacy of intra-articular injection of bone marrow concentrate in the treatment of symptomatic knee osteoarthritis in elderly patients, compared with a control group treated with hyaluronic acid injection (viscosupplementation).
Secondary objective: To assess whether there is a relationship between dose and efficacy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/06/2025, Comissão de Ética para a Saúde da Unidade Local de Saúde de Lisboa Ocidental - Health Ethics Committee of the Western Lisbon Local Health Unit (Unidade Local de Saúde de Lisboa Ocidental Hospital de Egas Moniz Rua da Junqueira, 126, Lisboa, 1349-019, Portugal; +351 210432665; anavalho@ulslo.min-saude.pt), ref: Approval code: 2025-76; RNEC registry number: 20170700050

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
After meeting elegibility criteria and signing informed consent, the participants will be assigned in 1 of 2 possible groups.
Intervention group (n = 45) - ultrasound guided iliac crest bone marrow aspiration and subsequent centrifugation, obtaining a concentrate (from which a sample is sent for analysis), followed by an ultrasound-guided injection into the knee joint
Control group (n = 45) - ultrasound-guided viscosupplementation (knee intra-articular injection of hyaluronic acid)

Participants will be randomly assigned in a 1:1 ratio to the intervention or control group using a computer-generated randomization, with different block sizes. Different investigators will be responsible for the randomization, the allocation process (with opaque sealed envelopes) and the treatment. There will be blinding of the investigators performing the assessments regarding the treatment that was administered

Besides demographic and medical background data, there will be clinical, functional and generic health status assessments, before the treatment and at 1, 3, 6, and 12 months afterwards. There will be imaging assessments before the treatment and at 6 and 12 months afterwards

Clinical assessments - knee pain Visual Analogue Scale (VAS), 10 meter walk test, Timed Up and Go Test, several knee physical exam parameters
Functional and generic health status assessment - WOMAC and EQ-5D-5L scales
Imaging assessment - X-ray (Kellgren-Lawrence scale and measurements) and MRI (WORMS score and measurements)

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
BioCUE®, Monovisc®

Primary outcome(s)
1. Knee pain measured using visual analogue scale (VAS) at baseline (pre-treatment) and at 1, 3, 6 and 12 months after treatment

Key secondary outcome(s))

Completion date
10/12/2027

Eligibility

Key inclusion criteria
1. Primary (idiopathic) femorotibial knee osteoarthritis (medial, lateral, or medial + lateral)
2. Diagnosis based on the clinical + radiographic criteria of the American College of Rheumatology for idiopathic knee osteoarthritis (knee pain + osteophytes + at least 1 of the following 3 criteria: age > 50 years, stiffness < 30 minutes, crepitus)
3. Knee symptoms mainly attributable to femorotibial osteoarthritis (medial, lateral, or medial + lateral), confirmed on physical examination
4. Pain and reduced lower limb mobility mainly attributable to the knee under study
5. Clinical presentation with average pain ≥ 5 (moderately severe) on the Visual Analogue Scale (VAS) for pain, on most days in the past month
6. Radiographic evidence of femorotibial osteoarthritis (medial, lateral, or medial + lateral) of Kellgren–Lawrence grade II or III, on a weight-bearing AP knee radiograph of the knee under study performed within the past year
7. Age ≥ 65 years

8. Willingness to participate in the study and sign the informed consent
9. If both knees meet the inclusion criteria, the knee selected for the study will be the one with the higher average pain on most days in the past month on the Visual Analogue Scale (VAS) for pain; if pain intensity is equal in both knees, the selected knee will be the one with more frequent pain (greater number of painful days in the past month)

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. History of knee surgery and of injection with platelet-rich plasma, or with bone marrow, adipose tissue, or umbilical cord concentrate
2. History of knee injection with hyaluronic acid or hylan within the past year
3. History of percutaneous invasive knee procedure in the past 3 months
4. Sepsis
5. Skin integrity alterations or infection of the knee or iliac crest
6. Inability to walk and perform transfers independently
7. Known immunosuppression, due to disease or therapy
8. Active oncological disease in the affected knee or in the iliac bone
9. Active infectious disease or fever
10. Depression
11. Fibromyalgia
12. Severe mental illness
13. Severe cognitive impairment

Date of first enrolment
26/11/2025

Date of final enrolment
10/12/2026

Locations

Countries of recruitment
Portugal

Study participating centre
Unidade Local de Saúde de Lisboa Ocidental
Estrada do Forte do Alto do Duque
Lisboa
Portugal
1449-005

Sponsor information

Organisation
Universidade Nova de Lisboa

ROR
https://ror.org/02xankh89

Organisation
Centro Hospitalar de Lisboa Ocidental

ROR
https://ror.org/036ypft38

Funder(s)

Funder type

Funder Name
Centro Clínico Académico de Lisboa (CCAL), Lisbon Clinical Academic Centre, Portugal

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available