ISRCTN12974924 https://doi.org/10.1186/ISRCTN12974924

The efficacy and safety of a high- concentration hybrid hyaluronic acid in patients with knee osteoarthritis: an open-label study

Submission date
03/10/2025

Recruitment status
No longer recruiting

Registration date
20/01/2026

Overall study status
Completed

Last Edited
20/01/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis is a common condition that causes joints to become painful and stiff, often due to the breakdown of cartilage and a reduction in natural joint lubricants like hyaluronic acid. This study is testing a treatment called Sinovial® HL 90, a type of hyaluronic acid that is injected directly into the knee joint. The aim is to see whether it helps improve joint movement, reduce pain, and delay the need for surgery in people with knee osteoarthritis.

Who can participate?
Adults diagnosed with moderate knee osteoarthritis (Kellgren–Lawrence grade 2–3) were eligible to take part in the study.

What does the study involve?
Participants received either one or two injections of Sinovial® HL 90 into their knee joint over a three-month period. The number of injections was decided based on each person's clinical assessment. Researchers then monitored changes in pain, movement, and overall quality of life over time.

What are the possible benefits and risks of participating?
The treatment may help reduce pain, improve joint function, and enhance quality of life. It could also help delay the need for surgery. As with any injection, there may be minor risks such as temporary discomfort, swelling, or infection at the injection site.

Where is the study run from?
The study was carried out at the Orthopaedic and Trauma Surgery Unit at Fondazione Policlinico Universitario Campus Bio-Medico in Rome, Italy.

When is the study starting and how long is it expected to run for?
November 2021 to November 2023

Who is funding the study?
IBSA Farmaceutici Italia.

Who is the main contact?
Dr Fabrizio Russo, fabrizio.russo@policlinicocampus.it

Contact information

Type(s)
Principal investigator

Contact name
Prof Biagio Zampogna

Contact details
Via Alvaro del Portillo 200
Roma
Italy
00128
+39 3334985912
b.zampogna@policlinicocampus.it

Type(s)
Scientific

Contact name
Dr Fabrizio Russo

ORCID ID
https://orcid.org/0000-0002-8566-8952

Contact details
Via Alvaro del Portillo 200
roma
Italy
00128
+39 3493601908
fabrizio.russo@policlinicocampus.it

Type(s)
Public

Contact name
Dr Andrea Autelitano

Contact details
Via della Filanda 30
lodi
Italy
26900

+39 3450908561
andrea.autelitano@ibsa.it

Additional identifiers

Protocol serial number
SINO90/01-20

Study information

Scientific Title
An open-label study to evaluate the efficacy and safety of a high-concentration hybrid hyaluronic acid, administered as a single dose and, in a secondary population, with repeated administration, in patients with knee osteoarthritis

Acronym
SINO90/01-20

Study objectives
Intra-articular injections of hybrid HA formulation, analysis of functional and quality of life outocome thug IKDC, KOOS, and SF-12 PCS questionnaires, pain assessment using VAS. Adverse event monitoring including classification by causality (unrelated, possibly, probably related), classification by severity (mild, moderate, severe), incident classification (serious, non-serious)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/12/2020, Comitato Etico dell'Università Campus Bio-Medico di Roma (Via Alvaro del Portillo 5, Roma, 00128, Italy; +39 0622548812; comitato.etico@unicampus.it), ref: 92/20 PAR ComEt CBM

Primary study design
Interventional

Study design
Prospective single-center open-label clinical study

Study type(s)
Efficacy, Safety, Treatment

Health condition(s) or problem(s) studied
Kellgren–Lawrence grade 2–3 knee Osteoarthrosis

Interventions
Single-dose (Population A) or repeated-dose (Population B) intra-articular injections of Sinovial® HL 90 (4.5%).

Population A: single injection of Sinovial® HL 90. The follow-up period lasted 6 months.
Population B: two or three intra-articular injections of Sinovial® HL 90 (4.5%) over the study

duration. This group included patients with very low International Knee Documentation Committee (IKDC) scores who, based on the investigator's judgment, were expected to benefit from this dosage schedule. The follow-up period lasted 6 months

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Sinovial® HL 90

Primary outcome(s)
Functional limitation and joint stiffness reduction, measured by the IKDC questionnaire, at 6 month

Key secondary outcome(s)
1. Functional limitation and joint stiffness are measured using the International Knee Documentation Committee (IKDC) questionnaire at baseline and 6 months in Population B
2. Pain is measured using a visual analog scale (VAS) at baseline, 3 months, and 6 months in both populations
3. Functional limitation is measured using the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire at baseline, 3 months, and 6 months in both populations
4. Quality of life is measured using the 12-item Short Form Health Survey – Physical Component Summary (SF-12 PCS) score at baseline, 3 months, and 6 months in both populations

Completion date
29/11/2023

Eligibility

Key inclusion criteria
1. Diagnosis of knee OA (medial, lateral, patellofemoral, bicompartmental, or tricompartmental)
2. Kellgren and Lawrence grade 2 or 3 on radiographic examination (scale 0–4)
3. Age range of 40–80 years
4. Willingness to participate in the study, demonstrated by signing an informed consent form.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Clinically significant abnormal laboratory values indicating disease
2. Confirmed allergy or suspected hypersensitivity to the investigated medical device and/or its excipients
3. A history of anaphylaxis due to drugs, dietary supplements, or any allergic reactions deemed by the investigator to potentially influence the study outcome
4. A significant medical history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, dermatological, hematological, endocrine, or neurological diseases that could interfere with the study's purposes
5. Use of herbal remedies and dietary supplements within 2 weeks prior to the study initiation
6. Prior treatment with corticosteroids, thyroid hormones, antibiotics, or antiepileptics
7. Any clinical condition deemed incompatible with participation by the investigator
8. Alcohol abuse
9. Women who were pregnant or breastfeeding
10. Patients using other intra-articular HA-based medical devices, non-steroidal anti-inflammatory drugs, or corticosteroid painkillers for their knee

Date of first enrolment
01/12/2021

Date of final enrolment
24/04/2023

Locations

Countries of recruitment
Italy

Study participating centre
Dipartimento di Ortopedia e Chirurgia del Trauma /Università Campus Bio-Medico
Via Alvaro del Portillo 200
Roma
Italy
00128

Sponsor information

Organisation
IBSA Farmaceutici (Italy)

ROR
https://ror.org/02cf8gj49

Funder(s)

Funder type
Industry

Funder Name
IBSA Farmaceutici Italia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from:
Fabrizio Russo
fabrizio.russo@policlinicocampus.it

IPD sharing plan summary
Available on request