

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
03/10/2025	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
20/01/2026	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
20/01/2026	Musculoskeletal Diseases	<input checked="" type="checkbox"/> 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### 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 outcome through 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

### Study design

Prospective single-center open-label clinical study

### Primary study design

Interventional

### Study type(s)

Efficacy, Safety, Treatment

### Health condition(s) or problem(s) studied

Kellgren–Lawrence grade 2–3 knee Osteoarthritis

## 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, bicompartamental, or tricompartamental)
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

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# 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

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## IPD sharing plan summary

Available on request