# Gait analysis of changes in clinical and biomechanical parameters in osteoarthritis knee patients after intra-articular infiltration with high molecular weight hyaluronic acid (Hyalubrix®)

Submission date	Recruitment status	Prospectively registered
26/05/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/07/2009	Completed	Results
Last Edited	Condition category	Individual participant data
21/07/2009	Musculoskeletal Diseases	☐ Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Cristina Smiderle

#### Contact details

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# Additional identifiers

Protocol serial number Q47 05 01

# Study information

## Scientific Title

Gait analysis of changes in clinical and biomechanical parameters in osteoarthritis knee patients after intra-articular infiltration with high molecular weight hyaluronic acid (Hyalubrix®): a randomised intra-patient comparison clinical study

## Study objectives

The goal of the research was to evaluate, in osteoarthritis of the knee patients, the efficacy of intra-articular high molecular weight hyaluronic acid (Hyalubrix®) with the use of gait analysis analysing both kinematics and kinetic parameters.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics Committee of San Bassiano Hospital approved on the 20th July 2005

## Study design

Randomised intra-patient comparison clinical study

## Primary study design

Interventional

## Study type(s)

Treatment

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

Knee osteoarthritis

### **Interventions**

The patients, after a complete verbal/questionnaire evaluation, clinical evaluation, anthropometric measurement evaluation (as prescribed by the Davis protocol), and an evaluation with the NRS and WOMAC scales, underwent the first round of gait analysis (T1). On the same day, after the instrumental analysis, the patients were given the first infiltration with hyaluronic acid: patients received three intra-articular injections once a week; the total duration of treatment was 14 days.

The control group was an intra-patient control group: the study product was administered in the OA knee while the controlateral knee was considered as intra-patient control group.

After 45 days from the first evaluation, the patients were assessed again with the NRS and WOMAC scales, and gait analysis.

## Intervention Type

Drug

### Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

**Hyalubrix®** 

## Primary outcome(s)

Improving walking parameters: GAIT Analysis, measured at baseline (T1), and after 45 days (T2).

## Key secondary outcome(s))

Reducing pain:

- 1. Western Ontario and McMaster Universities osteoarthritis (OA) index (WOMAC) scale
- 2. Numerical rating scale

Measured at baseline (T1), and after 45 days (T2).

## Completion date

11/05/2009

# Eligibility

## Key inclusion criteria

- 1. Aged at least 40 years old, either sex
- 2. Presence of grade 2 or 3 (according to the Kellegren and Lawrence scale) osteoarthritis (OA) of one knee
- 3. Knee with pain greater than 4 on the Numerical Rating Scale (NRS)

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## Key exclusion criteria

- 1. Concurrent presence of pathologies such as rheumatoid arthritis, gout, hip arthritis
- 2. Presence of skin infections near the knee
- 3. Use of corticosteroid in the last 3 months
- 4. Simultaneous anticoagulant therapy
- 5. Use of joint protective drugs
- 6. Clotting anomalies
- 7. Knee valgus
- 8. Known adverse reactions to hyaluronic acid
- 9. Presence of knee replacement or impending knee replacement surgery

## Date of first enrolment

20/07/2005

## Date of final enrolment

11/05/2009

# Locations

## Countries of recruitment

Italy

Study participating centre

Department of Physical Medicine and Rehabilitation

Bassano del Grappa, Vicenza

Italy

36061

# Sponsor information

## Organisation

Fidia Farmaceutici S.p.A. (Italy)

## **ROR**

https://ror.org/00dy5wm60

# Funder(s)

## Funder type

Industry

### **Funder Name**

Fidia Farmaceutici S.p.A. (Italy)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet

Participant information sheet 11/11/2025 11/11/2025 No