

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 contralateral 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 measure**

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

**Secondary outcome measures**

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).

**Overall study start date**

20/07/2005

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30 patients

**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)

**Sponsor details**

Via Ponte della Fabbrica 3/A

Abano Terme - Padova

Italy

35031

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**Sponsor type**

Industry

**Website**

<http://www.fidiapharma.it>

**ROR**

<https://ror.org/00dy5wm60>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Fidia Farmaceutici S.p.A. (Italy)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration