

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

Department of Physical Medicine and Rehabilitation
S.Bassiano Hospital
Bassano del Grappa, Vicenza
Italy
36061

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

Primary study design

Interventional

Study design

Randomised intra-patient comparison clinical study

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 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(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 Kellgren 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