ISRCTN48327946 https://doi.org/10.1186/ISRCTN48327946

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

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 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 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
ngiordan@fidiapharma.it

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