

Intra-articular injection of hyaluronic acid (MW 1500-2000 KDa; HyalOne®) in symptomatic osteoarthritis of the hip

Submission date 11/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/08/2013	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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_09_01

Study information

Scientific Title

Intra-articular injection of hyaluronic acid (MW 1500-2000 KDa; HyalOne®) in symptomatic osteoarthritis of the hip: a prospective cohort study

Study objectives

The aim of the study is to appraise rate and incidence of total hip replacement (THR) in patients suffering from hip osteoarthritis (OA), treated with ultrasound-guided intra-articular injections of Hyalubrix®.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Bioethics Committee of the Roman Province of Fatebenefratelli (Comitato di Bioetica della Provincia Romana dei FBF) approved on the 13/10/2008 (ref: 61/2008/C.B.)

Study design

Prospective cohort study

Primary study design

Interventional

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Patients suffering from hip osteoarthritis

Interventions

Ultrasound-guided intra-articular injections of hyaluronic acid (MW 1500-2000 KDa)

Injections were performed at least every 6 months, but some patients were treated as often as every 3 months.

The study follow-up visits were performed every 3 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Changes from baseline to the final visit with respect to Lequesne index

Secondary outcome measures

1. Changes from baseline to the final visit with respect to
 - 1.1. Visual Analogue Scale (VAS)
 - 1.2. Non-steroidal anti-inflammatory drug (NSAID) intake
2. Assessment of predictive indices for the response variables (lequesne and VAS indexes)

Overall study start date

13/10/2008

Completion date

13/12/2009

Eligibility**Key inclusion criteria**

1. Age > 40 years
2. Hip OA with joint pain of at least one years duration
 - 2.1. Symptomatic hip OA according to the American College of Rheumatology (ACR)
 - 2.2. Grade I, II, III or IV hip OA according to the Kellgren-Lawrence classification
 - 2.3. Evaluated on an X-ray taken no more than two months before enrolment

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

304

Key exclusion criteria

1. Concomitant use of oral anticoagulant therapy
2. Severe reduction of joint space narrowing evident on X-ray
3. Significant co-morbidities, hypersensitivity to HA or to avian proteins
4. Chronic systemic steroid treatment

Date of first enrolment

13/10/2008

Date of final enrolment

13/12/2009

Locations

Countries of recruitment

Italy

Study participating centre

Via Ponte della Fabbrica 3/A

Abano Terme

Italy

35031

Sponsor information

Organisation

Fidia Farmaceutici S.p.A (Italy)

Sponsor details

Via Ponte della Fabbrica 3/A

Abano Terme

Italy

35031

Sponsor type

Industry

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No