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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/05/2010	**Overall study status** Completed	
Last Edited 08/08/2013	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Nicola Giordan

Contact details
Via Ponte della Fabbrica 3/A
Abano Terme
Italy
35031

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