ISRCTN32694665 https://doi.org/10.1186/ISRCTN32694665

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

Registration date
20/05/2010

Overall study status
Completed

Last Edited
08/08/2013

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

Protocol serial number
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.)

Primary study design
Interventional

Study design
Prospective cohort study

Study type(s)
Treatment

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(s)
Changes from baseline to the final visit with respect to Lequesne index

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

Study outputs

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