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Intra-articular Hyalubrix® injections versus local anaesthetic in hip osteoarthritis

Submission date	Recruitment status	[ ] Prospectively registered
06/02/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/12/2020	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Q47-04-01

Study information

Scientific Title
Comparative, double blind, controlled study of intra-articular hyaluronic acid (Hyalubrix®) injections versus local anaesthetic in osteoarthritis of the hip

Study objectives
The study compared the benefit, duration and adverse event profile of intra-articular (IA) Hyalubrix® versus IA mepivacaine in the treatment of hip osteoarthritis (OA) using ultrasound-guidance to ensure IA injection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Clinical Study Protocol (CSP) with all its appendices, including informed consent documentation, insurance and Summary of Product Characteristics were submitted for evaluation and approval to the competent Ethic Committee in the involved centre. The study received the favourable opinion by the Ethic Committee on the 9th November 2004.

Study design
Single-site prospective randomised double-blind controlled clinical trial

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 contact Nicola Giordan at ngiordan@fidiapharma.it to request a patient information sheet

Health condition(s) or problem(s) studied
Hip osteoarthritis

Interventions
IA hip injections were guided by ultrasound using an anterosagittal in assistance of real-time ultrasound and Doppler imaging:
Active group: IA injection of Hyalubrix® 4 ml (2 syringes, 60 mg)
Control group: Mepivacaine 4 cc of 2%

Two treatment administrations: one at baseline, and the second one after one month.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hyalubrix®, mepivacaine

Primary outcome measure
Determination of the change in the Lequesne index of the hip, comparing IA Hyalubrix® to IA mepivacaine at 26 weeks.

Secondary outcome measures
Measured 90 and 180 days after first injection:
1. Pain intensity (recorded on a 10 cm VAS)
2. Patient record of non-steroidal anti-inflammatory drug (NSAID) consumption
3. Patients global assessment
4. Examining physician's global assessment
5. Demographic correlations to response
6. Hyaluronic acid (HA) safety

Overall study start date
09/11/2004

Completion date
30/06/2007

Eligibility

Key inclusion criteria
1. Aged greater than 40 years, either sex
2. Ambulant without assistance
3. Hip OA by American College of Rheumatology (ACR) radiographic criteria
4. Baseline Visual Analogue Scale (VAS) score of greater than 4 cm
5. Persistence of hip pain for at least 1 month before baseline
6. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40 participants (20 patients for arm)

Total final enrolment
42

Key exclusion criteria
1. Comorbidities (e.g. rheumatoid arthritis, avascular necrosis, fibromyalgia)
2. Infection around the injection site
3. Treatment with oral, parenteral, or IA steroids within 3 months
4. Use of anticoagulants or history of thrombocytopaenia
5. Allergy to local anaesthetics
6. History of adverse reaction to IA Hyalubrix®
7. Pending hip replacement surgery
8. Use of a purported OA disease modifying agent

Date of first enrolment
09/11/2004

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Italy

Study participating centre
Ospedale San Pietro FBF
Rome
Italy
00189

Sponsor information

Organisation
Fidia Farmaceutici S.p.A. (Italy)

Sponsor details
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Sponsor type

Industry

Website
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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	01/12/2009	30/12/2020	Yes	No