

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

<b>Submission date</b> 06/02/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/12/2020	<b>Condition category</b> 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

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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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 thrombocytopenia
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)

### 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?
<a href="#">Results article</a>	results	01/12/2009	30/12/2020	Yes	No