

The tolerability and efficacy of Hyalubrix® in osteoarthritis

Submission date 26/05/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/07/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/10/2011	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Prot. Q47.2005.01

Study information

Scientific Title

A prospective observational study of the tolerability and efficacy of injectable hyaluronic acid therapy (Hyalubrix®) in osteoarthritis

Acronym

PEGASO

Study objectives

Evaluation of the use of Hyalubrix®, under EC indications for registration, with particular reference to therapy tolerability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Azienda Ospedaliera Universitaria Policlinico Tor Vergata approved on the 20th June 2006
2. Comitato Etico Novara approved on the 9th June 2006 (ref: 1069/CE). Final approval given on the 27th July 2006 (ref: 1127/CE)

Study design

Observational prospective longitudinal multicentre study

Primary study design

Observational

Secondary study design

Cross-section survey

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Osteoarthritis

Interventions

Four visits were scheduled:

Visit one: enrolment and start of therapy

Visit two: during study treatment

Visit three: during study treatment

Visit four: patient's final evaluation, 2 weeks from third injection

At each visit, the following tools have also been adopted to evaluate the most significant effects of chronic pain on the social life and personality of the patient:

1. Pain at rest: Visual Analogue Scale (VAS)

2. Pain during motion: VAS
3. Functional Disability Index: Health Assessment Questionnaire (HAQ)
4. Quality of Life: EuroQoL

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Hyalubrix®

Primary outcome measure

Adverse event notification.

Timepoints:

Visit 0: at baseline

Visit 2: one week after baseline

Visit 3: one week after visit 2

Final visit: two weeks after visit 3

Secondary outcome measures

1. Evaluation of the medical device performance on pain during motion and at rest, determined by VAS and HAQ
2. Quality of life evaluation (by means of EuroQoL)

Timepoints:

Visit 0: at baseline

Visit 2: one week after baseline

Visit 3: one week after visit 2

Final visit: two weeks after visit 3

Overall study start date

28/08/2006

Completion date

12/01/2008

Eligibility

Key inclusion criteria

1. Patients suffering from degenerative or mechanical arthropathies who were candidates for being treated with Hyalubrix®
2. Patients aged 18 years or older, either sex
3. Patients who signed informed consent form

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1300 Patients - 50 doctors

Key exclusion criteria

1. Infections located in the body area to be treated
2. Established sensitivity to hyaluronic acid or to other components of the product

Date of first enrolment

28/08/2006

Date of final enrolment

12/01/2008

Locations**Countries of recruitment**

Italy

Study participating centre

Azienda Ospedaliera Universitaria

Rome

Italy

00133

Sponsor information**Organisation**

Fidia Farmaceutici S.p.A. (Italy)

Sponsor details

Via Ponte della Fabbrica 3/A

Abano Terme - Padova

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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	01/09/2011		Yes	No