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The tolerability and efficacy of Hyalubrix® in osteoarthritis

Submission date	Recruitment status	[_] Prospectively registered
26/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/07/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/10/2011	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
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
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Sponsor type
Industry

Website
http://www.fidiapharma.it

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