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Effects of Hymovis® injections in patients with osteoarthritis of the knee

Submission date
21/01/2015

Recruitment status
No longer recruiting

Registration date
11/02/2015

Overall study status
Completed

Last Edited
20/06/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The treatment for osteoarthritis (a disorder in which the joints become painful and stiff) consists of drugs (e.g., for pain relief) and non-drug treatments. Injections of hyaluronans, which are not drugs, into the knee is one of the well accepted standards of care for treating symptomatic knee osteoarthritis. The aim in this preliminary study is to assess the beneficial effect of Hymovis®, an innovative hydrogel formulation obtained from a hyaluronic acid derivative (HYADD4®), on the cartilage (soft bone tissue) of patients with knee osteoarthritis.

Who can participate?
Patients aged 40–75 years old with symptomatic knee osteoarthritis and

What does the study involve?
Patients will receive two treatment cycles of Hymovis® at 6 month intervals; each treatment cycle will consist of two intra-articular injections at 1 week intervals. They will have objective measurements of biological and MRI-based imaging markers.

What are the possible benefits and risks of participating?
A potential benefit for patients is relief of pain associated with knee osteoarthritis. The main risks are pain, swelling or infections due to the injection procedure.

Where is the study run from?
Centre Hospitalier Universitaire Brugmann (Belgium), Centre Hospitalier Universitaire Liège (Belgium), Hôpital Lariboisière (France) and Centre Hospitalier Régional Metz (France).

When is the study starting and how long it is expected to run for?
November 2014 to June 2017

Who is funding the study?
Fidia farmaceutici SpA (Italy)

Who is the main contact?
Professor Michel Malaise

Contact information

Type(s)
Public

Contact name
Mr Michel Malaise

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Additional identifiers

Protocol serial number
EQC5.14.02

Study information

Scientific Title
Evaluation of the biological and imaging markers of bone and cartilage degradation in patients with knee osteoarthritis receiving intra-articular injections of a hyaluronan derivative Hymovis®: a pilot study

Study objectives
Hymovis® acts on joints with osteoarthritis by inhibiting the key mechanisms leading to bone and cartilage degradation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Comité d'Ethique Hospitalier OM 26 (CHU Brugmann), 15/10/2014, Ref.: CE 2014/151
2. Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège, 12/11/2014, 2- Nr. Belge: B707201422130; Ref. 2014/247
3. Comité de Protection des Personnes Ile de France IV, 10/04/2015, Ref. CPP 2015/011
4. Comité d'Ethique Médicale (CHU UCL Mont-Godinne), 22/06/2015, Ref. 43/2015
5. Comité d'Ethique 412 (CHR Citadelle), 17/06/2015, Ref. 1515
6. Agence Nationale de Sécurité du Médicament et des produits de santé, 06/05/2015, ID-RCB : 2015-A00370-49

Primary study design
Interventional

Study design
Open-label multicentre pilot study

Study type(s)
Treatment

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

Interventions
1. Each patient will be enrolled in the study for 13 months (nine visits)
2. Patients will receive two treatment cycles of Hymovis® at 6 month intervals; each treatment cycle corresponds to two intra-articular injections at 1 week intervals

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hymovis

Primary outcome(s)
Variation in type II collagen-specific biomarkers: levels will be measured at screening visit, follow-up visits after 1 month and 3 months, and last visit after 12 months

Key secondary outcome(s)
1. Variation in biomarkers related to cartilage homoeostasis: levels of biomarkers will be measured at the screening visit, follow-up visits after 1 month and 3 months, and at the last visit after 12 months
2. Variation in magnetic resonance imaging (MRI) markers: measured at the screening visit and after 12 months
3. Variation in pain and function: measured with the visual analogue scale at the screening visit, follow-up visits after 1 month and 3 months, and at the last visit after 12 months
4. Response to treatment: measured with the OMERACT–OARSI (Outcome Measures in Rheumatology–Osteoarthritis Research Society International) set of responder criteria at the screening visit, follow-up visits after 1 month and 3 months, and last visit after 12 months
5. Tolerance and satisfaction: measured with adverse events and drop-off rates at the screening visit, follow-up visits after 1 month and 3 months, and end visit after 12 months

Completion date
30/06/2017

Eligibility

Key inclusion criteria

1. Age 40–75 years old
2. Monolateral (unless contralateral knee is grade I and asymptomatic) femorotibial knee osteoarthritis associated or not with femoropatellar knee osteoarthritis
3. Clinical and radiological criteria of the American College of Rheumatology
4. Symptomatic for more than 6 months in the most painful knee
5. Radiological Kellgren and Lawrence grade II or III in radiographs from less than 12 months ago
6. Mean knee pain score of the most painful knee at rest over the past 24 hours on the Visual Analogue Scale (0–100) of at least 40 with a washout period for Paracetamol and oral non-steroidal anti-inflammatory drugs depending on the half-life of the drug
7. Able to follow the instructions of the study
8. Signed an informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Bilateral (except asymptomatic and grade I) osteoarthritis of the knee
2. Radiological Kellgren and Lawrence grade I or IV
3. Chondromatosis or villonodular synovitis of the knee
4. Recent trauma (<1 month) of the symptomatic knee
5. Acute inflammatory osteoarthritis
6. Articular disease resulting from articular dysplasia, aseptic osteonecrosis, acromegaly, Paget's disease, haemophilia or haemochromatosis
7. Inflammatory disease
8. Pathologies interfering with the evaluation of osteoarthritis
9. Contraindications to Hymovis®: hypersensitivity to the product components and infections or skin diseases in the area of the injection site
10. Anticoagulants (coumarinic compounds) and heparin

Date of first enrolment
25/11/2014

Date of final enrolment
25/04/2016

Locations

Countries of recruitment

Belgium

France

Study participating centre
Centre Hospitalier Universitaire Brugmann
4 Place A. Van Gehuchten
Brussels
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1020

Study participating centre
Centre Hospitalier Universitaire Liège
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Centre Viggo Petersen Inserm UMR 1132
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
Fidia Farmaceutici Spa

ROR
https://ror.org/00dy5wm60

Funder(s)

Funder type
Industry

Funder Name
Fidia Farmaceutici Spa (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	18/06/2019	20/06/2019	Yes	No