

Intra-articular hyaluronic acid and chondroitin sulfate in osteoarthritis of the knee

Submission date 16/12/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/04/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 13/10/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Osteoarthritis is a condition that causes joints to become painful and stiff. In the treatment of osteoarthritis, it is now agreed that surgical procedures should be at least delayed, and even avoided as far as possible. Hyaluronic acid is found in the synovial fluid in joints and acts as both a lubricant and shock absorber. Hyaluronic acid can be injected into the joint (intra-articular injections) to improve joint lubrication. Structovial CS is the only one of the currently available solutions to treat knee osteoarthritis that combines chondroitin sulphate and hyaluronic acid (HA/CS). Chondroitin sulfate is a chemical that is normally found in cartilage around joints in the body. The aim of this study is to assess the effectiveness of three weekly intra-articular injections of HA/CS in knees affected by osteoarthritis.

Who can participate?

Patients aged between 45 and 80 with osteoarthritis of the knee

What does the study involve?

All participants receive three intra-articular injections of HA/CS over a 3-week period. Pain and knee function are assessed over a period of 12 weeks.

What are the possible benefits and risks of participating?

HA/CS may improve participants' health and physical function. There are no known risks to participants.

Where is the study run from?

The study takes place at various rheumatological clinics at hospitals and at private centres in France and Belgium

When is the study starting and how long is it expected to run for?

March to October 2008

Who is funding the study?

Pierre Fabre Research Institute (France)

Who is the main contact?
Prof. Thierry Appelboom

Contact information

Type(s)
Scientific

Contact name
Prof Thierry Appelboom

Contact details
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1070

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V00220 IA 402

Study information

Scientific Title
Evaluation of a medical device comprising hyaluronic acid and chondroitin sulfate for intra-articular use in patients suffering from femorotibial osteoarthritis of the knee

Study objectives
Evaluate the efficacy of three weekly intra-articular injections of hyaluronic acid/chondroitin sulfate in knees affected by femoro-tibial osteoarthritis over a period of 12 weeks

Ethics approval required
Old ethics approval format

Ethics approval(s)
Erasme Hospital Ethics Committee, University Libre of Bruxelles, Belgium [Le Comite dEthique Hopital Erasme], 20/12/2007

Study design

Single-center open-label phase IV study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Osteoarthritis of the knee

Interventions

Three weekly intra-articular injections of HA/CS in knees affected by femoro-tibial osteoarthritis over a 3 week period

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Chondroitin sulphate, hyaluronic acid

Primary outcome measure

Pain (VAS) and function (Lequesnes Algo-Functional Knee Index) over a period of 12 weeks

Secondary outcome measures

1. Ultrasound parameters (joint effusion, synovial and popliteal cysts)
2. OA biomarkers of inflammation [IL-6], degradation [Coll2-1] and synthesis [CPII] of collagen type II, degradation of aggrecan [CS846], and markers of oxidative stress [Coll2-1NO2]

Overall study start date

10/03/2008

Completion date

13/10/2008

Eligibility

Key inclusion criteria

1. Male or female patients aged between 45 and 80 years
2. Suffering from internal and/or external femoro tibial OA:
 - 2.1. Meeting the criteria of the American College of Rheumatology (ACR)
 - 2.2. Lasting for at least 6 months
 - 2.3. Pain \geq 40mm as measured on a visual analogue scale (VAS)
 - 2.4. Stage Kellgren and Lawrence II or III
3. OA deemed to justify a treatment with intra articular HA according to the investigator
4. Patients written informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Symptomatic femoro-patellar arthrosis or hip arthrosis on the same side, concomitant skeletal disease (Paget disease, rheumatoid arthritis, ankylosing spondylitis)
2. Former or concomitant treatment (intra-articular corticosteroids, topical or oral NSAIDs, anti-arthritis slow acting treatment, recent surgery)
3. Individual characteristics incompatible with a drug trial (pregnancy or lack of contraception, serious concomitant disease, participation in a clinical trial within the preceding 30 days)

Date of first enrolment

10/03/2008

Date of final enrolment

13/10/2008

Locations**Countries of recruitment**

Belgium

Study participating centre

Erasmus Hospital Ethics Committee

Brussels

Belgium

1070

Sponsor information

Organisation

Pierre Fabre Research Institute [Institut de Recherche Pierre Fabre] (France)

Sponsor details

3 Avenue Hubert Curien
Toulouse
France
31035

Sponsor type

Research organisation

Website

<http://www.pierre-fabre.com/>

ROR

<https://ror.org/04hdhz511>

Funder(s)

Funder type

Industry

Funder Name

Pierre Fabre Research Institute (France)

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?
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[Results article](#)

results

04/08/2012

Yes

No