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

Submission date
16/12/2011

Recruitment status
No longer recruiting

Registration date
04/04/2012

Overall study status
Completed

Last Edited
13/10/2016

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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 > = 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
Erasme 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?

Results article	results	04/08/2012	Yes	No