Effect of Structum® (chondroitin sulfate) on cartilage volume in knee osteoarthritis

Submission date	Recruitment status	Prospectively registered		
28/04/2011	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/06/2011	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
21/03/2013	Musculoskeletal Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers L00023 GE 403

Study information

Scientific Title

Effect of 12 months treatment with Structum® (chondroitin sulfate) on cartilage volume in knee osteoarthritis patients: a randomised, double-blind, placebo-controlled pilot study using magnetic resonance imaging (MRI)

Study objectives

There is a correlation between clinical symptoms and decrease of cartilage volume in patients suffering from knee osteoarthritis (KOA).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Advisory Committee for the Protection of Persons in Biomedical Research [Comité Consultatif pour la Protection des Personnes dans la Recherche Biomédicale (Ethics Committee)] of Toulouse 1 approved on 19th May 2004

Study design

Multicentre randomised double-blind placebo-controlled parallel group study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Knee osteoarthritis

Interventions

- 1. Group Structum®: 1 capsule (500mg chondroitin sulfate) two times a day (b.i.d) for 12 months.
- 2. Group Placebo: 1 capsule Placebo two times a day (b.i.d)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Structum® (chondroitin sulfate)

Primary outcome measure

The correlation between the evolution of clinical symptoms (Lequesne Index and VAS pain) and the total volume of cartilage after 12 months treatment

Secondary outcome measures

- 1. Mean evolution from baseline of the total volume of cartilage and of each knee compartment
- 2. Evolution of other morphological osteo-articular lesions (sub-chondral oedema, meniscal lesions, synovitis)
- 3. Mean variation of the pain score (VAS) and of the Lequesne Index
- 4. Patients and investigators global assessment scores

Overall study start date

31/08/2004

Completion date

08/06/2006

Eligibility

Key inclusion criteria

- 1. Patients aged from 50 to 75 years
- 2. Symptomatic femorotibial KOA fulfilling American College of Rheumatology (ACR) criteria for KOA
- 3. A Kellgren-Lawrence radiological grade II or III
- 4. A global pain score greater than or equal to 30 on a 100mm Visual Analogue Scale (VAS)

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

40 patients

Key exclusion criteria

- 1. Isolated symptomatic femoropatellar osteoarthritis of the knee
- 2. Inflammatory, infectious or metabolic arthritis
- 3. Contraindication to MRI examination
- 4. Intra-articular steroid injection or hyaluronic acid injections in the 3 months preceding inclusion
- 5. Non steroidal anti-inflammatory drugs (NSAIDs) in the 2 days preceding inclusion

Date of first enrolment

31/08/2004

Date of final enrolment

08/06/2006

Locations

Countries of recruitment

France

Study participating centre Service Central de Radiologie et dImagerie Médicale

Toulouse France 31059

Sponsor information

Organisation

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

Sponsor details

Address 3 Avenue Hubert Curien Toulouse France 31035

Sponsor type

Industry

Website

http://www.pierre-fabre.com

ROR

https://ror.org/04hdhz511

Funder(s)

Funder type

Industry

Funder Name

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	01/09/2012		Yes	No