

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

Submission date 28/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/06/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/03/2013	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Multicentre randomised double-blind placebo-controlled parallel group study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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 d'Imagerie Médicale

Toulouse

France

31059

Sponsor information

Organisation

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

ROR

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

Funder(s)

Funder type

Industry

Funder Name

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

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	01/09/2012		Yes	No