

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

<b>Submission date</b> 28/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/03/2013	<b>Condition category</b> 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

**Study design**

Multicentre randomised double-blind placebo-controlled parallel group study

**Primary study design**

Interventional

**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?
<a href="#">Results article</a>	results	01/09/2012		Yes	No