ISRCTN33423639 https://doi.org/10.1186/ISRCTN33423639

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

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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

Pierre Fabre Research Institute (Institut de Recherche Pierre Fabre) (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	01/09/2012		Yes	No