

Efficacy and safety of two Chondroitin Sulfate preparations in patients with symptomatic osteoarthritis of the knee

Submission date 07/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/04/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/12/2020	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

Study website

http://www.pfclintrial.com/public/clinical-trials/html/en/trials_register/index.php

Contact information

Type(s)

Scientific

Contact name

Prof Patrice Fardellone

Contact details

Service de Rhumatologie
CHU Nord
Amiens
France
80054

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Comparative study of efficacy and safety of Structum® and Chondrosulf® in patients with symptomatic osteoarthritis of the knee: a multicentre, randomised, double-blind, double placebo-controlled, parallel group study

Acronym

Structum® vs Chondrosulf® study

Study objectives

Structum® is non-inferior to Chondrosulf® on pain relief and functional improvement in patients with symptomatic knee osteoarthritis (OA) after 6 month of treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Committee for the Protection of Persons (CPP) NORTHWEST II (Comité de Protection des Personnes (CPP) NORD-OUEST II), approved on 28 March 2008

Study design

Multicentre randomised double-blind double 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

Osteoarthritis of the knee

Interventions

Group Chondrosulf® 1 capsule (400mg Chondroitin) three times a day (t.i.d), i.e.1200mg/day

Group Structum®, : 1 capsule (500mg Chondroitin) two times a day (b.i.d), i.e.1000mg/day

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Structum®, Chondrosulf®

Primary outcome measure

Two co-primary efficacy endpoints :

1. Mean variation of the global pain score (VAS) over 24 weeks
2. Mean variation of Lequesne Index over 24 weeks

Secondary outcome measures

1. Responders (OARSI-OMERACT criteria)
2. Patients and investigators global assessment scores
3. Consumption of analgesics medication (including NSAIDs)
4. Quality of life assessment (SF12 & OAKHQOL)

Overall study start date

15/09/2008

Completion date

17/06/2009

Eligibility

Key inclusion criteria

Patients aged from 50 to 80 years with symptomatic femorotibial knee OA fulfilling American College of Rheumatology (ACR) criteria for knee OA, with a Kellgren-Lawrence radiological grade II or III, a global pain score greater than or equal to 40 on a 100mm Visual Analogue Scale (VAS) and a Lequesne Index greater than or equal to 7

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned: 800 patients

Total final enrolment

837

Key exclusion criteria

1. Isolated symptomatic femoropatellar osteoarthritis of the knee
2. Symptomatic hip OA homolateral to the target knee
3. Inflammatory, infectious or metabolic arthritis
4. Bisphosphonates or strontium ranelate in the 3 months preceding inclusion
5. Corticosteroid treatment during the month preceding inclusion
6. Intra-articular steroid injection in the 2 months preceding inclusion
7. Intra-articular hyaluronic acid in the 6 months preceding inclusion
8. Non steroidal anti-inflammatory drugs (NSAIDs) in the 2 days preceding inclusion
9. Articular lavage of target knee in the 3 months preceding inclusion

Date of first enrolment

15/09/2008

Date of final enrolment

17/06/2009

Locations

Countries of recruitment

France

Study participating centre**Service de Rhumatologie**

Amiens

France

80054

Sponsor information

Organisation

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

Sponsor details

3, Avenue Hubert Curien

Toulouse

France

31035

Sponsor type

Industry

Website

<http://www.pierre-fabre.com>

ROR

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	01/06/2013	18/12/2020	Yes	No