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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

Registration date
12/04/2011

Overall study status
Completed

Last Edited
18/12/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

L00023 GE 409

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

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