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Effect of chondroitin sulfate on soluble biomarkers of osteoarthritis

Submission date
28/09/2015

Recruitment status
No longer recruiting

Registration date
02/10/2015

Overall study status
Completed

Last Edited
10/10/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Cartilage is the protective surface that allows your joints to move smoothly. Osteoarthritis (OA) is a condition where the cartilage in the joints breaks down, causing pain. The challenge has not only been to find a cure for OA but also to identify tools which could help the diagnosis and monitoring of the progression of the disease and the effectiveness of treatment. Those tools need to be accurate for the monitoring of progression of the disease and sensitive enough to identify early disease. Biomarkers (biological markers) are among those possible tools. Changes in the level of biomarkers of cartilage breakdown could help not only for the diagnosis but also for the monitoring of OA progression or treatment. The aim of this study is to investigate the effects of chondroitin sulfate (CS), a symptomatic slow-acting drug for OA, on the blood levels of biomarkers in patients with knee OA.

Who can participate?
Knee OA patients over 40 years of age.

What does the study involve?
Participants are treated with CS over 6 months and followed to find out about changes in symptoms (pain and function) as well as changes in blood biomarkers related to cartilage breakdown. Five visits are scheduled for each patient and blood samples are collected at each visit.

What are the possible benefits and risks of participating?
Participants could benefit from improved symptoms and personalized treatment. The results will also help scientists to better understand the role of biomarkers in OA and their usefulness in the monitoring of the disease and the effectiveness of treatment. Blood samples are routinely taken during visits to the doctor and the risk is minor. The participants could just experience a small swelling or inflammation in the arm area where the needle is inserted.

Where is the study run from?
Rheumatology Poal Institute of Barcelona (Spain)

When is the study starting and how long is it expected to run for?
November 2011 to January 2014

Who is funding the study?
Bioiberica S.A. (Spain)

Who is the main contact?
Helena Martinez

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BIO-CON-2012-01

Study information

Scientific Title
Post-authorization open-label study in knee osteoarthritis patients receiving chondroitin sulfate 800 mg daily during 6 months

Study objectives
Osteoarthritis (OA) is one of the most common forms of musculoskeletal disorders. It is one of the major cause of pain and disability in the adult population. The challenge for the last few decades for OA has not only been to find a cure but also to identify tools which could help the diagnosis and monitoring of disease progression and the efficacy of therapeutic interventions. Those tools need to be accurate for the monitoring of structural progression of the disease and sensitive enough to identify early events at the molecular level.

Changes in the level of biomarkers specific of cartilage metabolism could help not only for the diagnosis but also for the monitoring of osteoarthritis progression or therapeutic intervention. The aim of this study was to investigate the effects of chondroitin sulfate on the serum levels of biomarkers in patients with knee osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IDIAP (Primary Care Research Institute) Jordi Gol i Gurina, 08/08/2012

Study design
Single-centre observational post-authorization study

Primary study design
Observational

Secondary study design
Post-authorization study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
Seventy two patients with unilateral symptomatic knee OA were involved in a post-authorization open-label study. Patients treated with chondroitin sulfate (CS; 800 mg/day) were evaluated 5 times from D-30 to 6 months.

Intervention Type

Primary outcome measure
Percentage relative change in serum biomarkers (Coll2-1, Coll2-1NO2, Fib3-2) measured at five visits: selection visit (D-30 days), baseline visit (D0, initiation of treatment), 1-month visit, 3-month visit and 6-month visit.

Secondary outcome measures
1. Evaluation of pain through a visual analogue scale of 10 cm (VAS)
2. Evaluation of knee function disability measured by Lequesne Algofunctional Index

Measured at five visits: selection visit (D-30 days), baseline visit (D0, initiation of treatment), 1-month visit, 3-month visit and 6-month visit.

Overall study start date
30/11/2011

Completion date
10/01/2014

Eligibility

Key inclusion criteria
1. Patients of both sexes and over 40 years of age diagnosed with unilateral symptomatic osteoarthritis of the knee who met the criteria of the American College of Rheumatology (ACR)
2. Patients who were rated grade II or III on the Kellgren and Lawrence radiological scale
3. Patients with symptomatic osteoarthritis with a pain in the knee > 40 mm on a Visual Analogue Scale (VAS) for pain assessment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
72

Key exclusion criteria
1. Women who were pregnant or breastfeeding.
2. Patients with any form of decompensated or uncontrolled heart disease, diagnosed with renal or liver failure, severe infections, decompensated asthma, or a history of either alcoholism or another drug addiction and/or uncontrolled active psychiatric disorder.
3. Patients who were grade I or IV on the Kellgren and Lawrence radiological scale.
4. Patients with bilateral symptomatic knee osteoarthritis or symptomatic and developing osteoarthritis in 3 or more joints, including the knee targeted in the study.
5. Patients who have had a prosthesis replaced in the 12 months prior to inclusion.
6. Concurrent joint rheumatisms (history and/or presence of signs at the time of selection) that could give rise to a misinterpretation of the evaluation of efficacy against pain or interfere in the evaluation, such as chondrocalcinosis, Paget’s disease of the limb which is ipsilateral in relation to the affected knee, rheumatoid arthritis, aseptic osteonecrosis, gout, septic arthritis, ochronosis, acromegaly, hemochromatosis, Wilson’s disease, osteochondromatosis, seronegative spondiloarthropathy, mixed conjunctival tissue disease, collagen vascular disease, psoriasis, inflammatory bowel disease.
7. Fibromyalgia patients.
8. Patients who performed intense physical activity.
9. Patients with an osteotomy in the study knee.
10. Arthroscopy in the previous 3 months.
11. Patients with a contraindication for the use of chondroitin sulphate.
12. Patients who have used hyaluronic acid (intra-articular hyaluronic acid in the affected knee) during the 26 weeks prior to inclusion.

13. Patients who have received intra-articular corticoid infiltrations in either of their hips or knees in the three months prior to the intervention.
14. Patients who had received oral corticoids in the three months prior to starting the study.
15. Patients who had taken any of the drugs classified as SYSADOA in the three months prior to the baseline visit.
16. Patients who had taken oral and/or topical NSAIDs (including COXIBs) at anti-inflammatory doses during the 30 days prior to the baseline visit.
17. Patients who had used medicinal plants or homeopathic products and analgesic creams or gels during the week prior to inclusion.

Date of first enrolment
23/10/2012

Date of final enrolment
03/06/2013

Locations

Countries of recruitment
Spain

Study participating centre
Rheumatology Poal Institute of Barcelona
Spain
08022

Sponsor information

Organisation
Bioiberica S.A.

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08029

Sponsor type
Industry

Website
https://www.bioiberica.com/index/es/

ROR
https://ror.org/057p4eb38

Funder(s)

Funder type
Industry

Funder Name
Bioiberica S.A. (Spain)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/10/2016		Yes	No