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Study to evaluate the effect of chondroitin sulfate on the synovitis in patients with knee osteoarthritis

Submission date
27/10/2014

Recruitment status
No longer recruiting

Registration date
20/11/2014

Overall study status
Completed

Last Edited
20/11/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis is a condition that causes joints to become painful and stiff. It is caused by damage in and around the joint that the body is unable to fully repair. It affects about 3.6% of the world's population. It can cause chronic disability and is associated with increased healthcare and socioeconomic costs. The pain and disability associated with the disease are due to articular (joint) inflammation, cartilage degradation (a flexible connective tissue covering the bones of the joint) and new bone formation at the joint edges. Here, we want to explore the effect of chondroitin sulfate (CS) – a important structural component of cartilage - on joint inflammation as measured by the diagnostic imaging technique ultrasonography. We also plan to contribute to the understanding of the possible mechanisms involved in this anti-inflammatory effect.

Who can participate?
Adults aged at least 40 and diagnosed with osteoarthritis.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given 800mg of CS (Condrosan®), once a day for 6 months. Those in group 2 are given 3g of ACT (Acetaminophen) once a day for 6 months. Both treatments are then stopped to assess the long-lasting effects of CS during the next 3 months. Patients are allowed to take tramadol (a pain killer) up to 112.5mg/day. They are all examined at the start of the study, and then after 1.5 months, 3 months, 6 months and, finally, 9 months. At their first visit, knee radiography is performed to see how badly it is affected by the osteoarthtitis. Subsequent follow up examinations involve a physical exam, ultrasonography (US), knee pain using a patient's self-assessed 10 cm visual analogue scale (VAS), any improvement in the function of the knee, arthrocentesis (removing fluid from the joint) and taking blood samples.

What are the possible benefits and risks of participating?
Patients will not directly benefit from the study but they will help to improve osteoarthritis management, as we need objective results of the effect of chondrotin sulfate in knee inflammation. Any side effects are due to the two treatments used in the study and also from

the arthrocentesis procedure. Chondroitin sulfate can cause upset stomach, nausea, heartburn, and diarrhea. Acetaminophen side effects include passing blood in urine or stools, fever, sharp pain in the lower back or side, skin rashes, itching, sore throat, sores, ulcers, white spots on the lips or in the mouth, sudden fall in the amount of urine, unusual bleeding or bruising, unusual tiredness or weakness and yellow eyes or skin. Risks associated with the arthrocentesis procedure include infection of the joint, bleeding into the joint, increased pain and an allergic reaction.

Where is the study run from?
Rheumatology service, Hospital del Mar, Barcolona (Spain)

When is study starting and how long is it expected to run for?
October 2008 to October 2010

Who is funding the study?
Rheumatology service, Hospital del Mar, Barcolona (Spain)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Study information

Scientific Title
Pilot, open-label, prospective, longitudinal, parallel study to evaluate the effect of chondroitin sulfate treatment effect in synovitis measured by ultrasonography in knee osteoarthritis patients

Acronym
N/A

Study objectives
It is hypothesized that the treatment with chondroitin sulfate reduce the knee synovial membrane inflammation present in osteoarthritis. This reduction is accompanied by pain and function improvement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The research ethics review committee of IMAS-Hospital del Mar; 04/02/2008; ref: 2007/2846/I

Primary study design
Interventional

Study design
Nine months pilot open-label prospective longitudinal parallel study

Study type(s)
Treatment

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

Interventions
The participants will be randomly assigned to one of 2 study groups:
1. Chondroitin sulfate: 800mg orally once daily
2. Acetaminophen: 3g orally once daily
Both treatments will be taken for 6 months and both grups will be followed up for 9 months

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
1. Chondroitin sulfate 2. Acetaminophen

Primary outcome(s)
Synovial hypertrophy and effusion measured by ultarsonography. The patient will be examined with the knee in 45 degree flexion and in full extension. The maximal values for synovitis and effusion will be measured in millimetres (mm) in the suprapatellar recess in the longitudinal axis using a 7-12 MHz linear array probe. All measurements will be carried out by the same investigator, who will be blind to the patients treatment regimen.

Key secondary outcome(s)
1. Pain of the studied knee using a patients self-assessed 10 cm visual analogue scale (VAS)
2. Joint function improvement using the Lequesne index
3. Synovial and serum human ILs (IL-1b, IL-6, and IL-8), chemokines (CXCL16, MCP-1, RANTES, and fractalkine) and neuropeptides (VIP, CRF, and UCN) levels will be measured through Luminex-based multiplex assay, ELISA and enzyme immunoassay kits

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. Men or women 40 years or older
2. Fulfilment of the American College of Rheumatology (ACR) classification criteria for clinical KOA
3. Presence of radiographic OA in the knee joint, defined as a Kellgren and Lawrence (K&L) score of 2 or 3.
4. Ultrasonography presence of synovitis plus joint effusion thickness ≥4 mm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any serious disease (such as decompensate heart disease, diabetes, fibromyalgia, renal insufficiency, liver disease or malignancies)
2. Secondary OA
3. Use of any medication already know to affect the variables examined (oral corticosteroids, intra-articular corticosteroids, or any SYSADOA within 3 previous months before study enrolment, or any nonsteroidal anti-inflammatory drug within 30 days before studys enrolment)

Date of first enrolment
01/10/2008

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
Spain

Study participating centre
Hospital del Mar
Passeig Marítim de la Barceloneta, 25-29
Barcelona
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Sponsor information

Organisation
Hospital del Mar (Spain)

ROR
https://ror.org/03a8gac78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
IMAS-Hospital del Mar (Spain) - Rheumatology Service

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration