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Glucosamine in osteoarthritis: long-term effectiveness

Submission date	Recruitment status
14/01/2005	No longer recruiting
Registration date	**Overall study status**
08/03/2005	Completed
Last Edited	**Condition category**
22/02/2008	Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym
GOAL

Study objectives
Pharmacological treatment for osteoarthritis (OA) can be divided into two groups: symptom-modifying drugs and disease-modifying drugs. Symptom-modifying drugs are currently the prescription of choice for patients with OA, as disease-modifying drugs are not yet available in usual care. However, there has recently been a lot of debate about glucosamine sulphate (GS), a biological agent that is thought to have both symptom-modifying and disease-modifying properties. This assumption has yet to be proved. This blind randomised clinical trial examines the long-term symptom-modifying and disease-modifying effectiveness of GS in patients with hip OA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trial approved by the Medical Ethics Committee at the Erasmus MC - University Medical Centre Rotterdam.

Study design
Randomised, blinded, placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients are randomised to either 1500 mg of oral glucosamine sulphate or a placebo daily for the duration of two years.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Glucosamine

Primary outcome(s)
The primary outcome measures, which are joint space narrowing (JSN), and change in the pain and function score of the Western Ontario McMaster Universities Osteoarthritis index

(WOMAC), are determined at baseline and after two years of follow-up during the final assessment. Intermediate measures at three-month intervals throughout the trial are used to study secondary outcome measures.

Key secondary outcome(s))
Secondary outcome measures are changes in WOMAC stiffness score, quality of life, medical consumption, side effects and differences in biomarker CTX-II.

Completion date
31/03/2006

Eligibility

Key inclusion criteria
Patients are eligible for participation when they meet one of the American College of Rheumatology (ACR) criteria for osteoarthritis of the hip.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients that have already undergone hip replacement surgery
2. Patients on the waiting list for hip replacement surgery
3. Patients that have a Kellgren-Lawrence score of 4
4. Patients with renal or hepatic disease or diabetes mellitus or a disabling co-morbidity

Date of first enrolment
01/10/2003

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
Netherlands

Study participating centre

Department of General Practice, room Ff320
Rotterdam
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Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (The Netherlands) - Breedtestrategie

Results and Publications

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	19/02/2008		Yes	No
Protocol article	Study protocol	26/04/2005		Yes	No