

Glucosamine in osteoarthritis: long-term effectiveness

| | | |
|--|---|---|
| Submission date 14/01/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 08/03/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 22/02/2008 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sita M.A. Bierma-Zeinstra

Contact details
Department of General Practice, room Ff320
Erasmus MC
PO Box 2040
Rotterdam
Netherlands
3000 CA
+31 (0)10 408 7633
s.bierma-zeinstra@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/10/2003

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

Age group

Adult

Sex

Both

Target number of participants

222

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

Netherlands

3000 CA

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

Sponsor details

Board of Directors

PO Box 2040

Rotterdam

Netherlands

3000 CA

+31 (0)10 463 2578

c.festen@erasmusmc.nl

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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? |
|----------------------------------|----------------|--------------|------------|----------------|-----------------|
| Protocol article | Study protocol | 26/04/2005 | | Yes | No |
| Results article | Results | 19/02/2008 | | Yes | No |