Disease modifying activity of celecoxib on articular cartilage in osteoarthritis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25692

Source
NTR

Brief title
Disease modifying activity of celecoxib.

Health condition

end stage knee osteoarthritis

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis hospital Rotterdam
Source(s) of monetary or material Support: UMC Utrecht

Intervention

Outcome measures

Primary outcome

Difference in proteoglycan release of the OA cartilage under the influence of celecoxib.

Secondary outcome

Changes in several biochemical and histochemical characteristics of the OA cartilage

including proteoglycan synthesis rate, proteoglycan content, prostaglandin E2 production, and COX-1 and COX-2 expression of cartilage.

Study description

Background summary

The objective of the study is to evaluate, in patients with end stage knee osteoarthritis, the in vivo disease (tissue structure) modifying activity of celecoxib, as a selective COX-2 inhibitor, in addition to its inflammation regulatory properties, compared to naproxen as a conventional non-selective NSAID.

This is a blind randomized controlled study.
Patients with knee osteoarthritis, who are eligible for and on the waiting list for total knee replacement surgery are asked to participate. Patients will be assigned to one of the four groups:

One group receives no treatment for 4 weeks, the second group receives 2x daily 200 mg celecoxib for 4 weeks until surgery, the third group receives 2 x daily 200 mg celecoxib for 4 weeks until 3 days before the surgery and the fourth group receives 3 x daily 250 mg naproxen for 4 weeks until 3 days before the surgery. Each group will consist of 43 patients.

Before trial medication starts and at the day of surgery a sample of blood and urine will be taken for biomarker analysis. In addition a WOMAC questionnaire and VAS pain will be evaluated at these timepoints. The knee replacement surgery will take place as scheduled. Cartilage and synovial tissue that are removed as standard procedure during replacement surgery will be used for analyses to evaluate the disease modifying activity in the four groups.

Study objective

Celecoxib, as a selective COX-2 inhibitor, has in vivo disease modifying activity in addition to its inflammation regulatory properties, in comparison to naproxen as a conventional non-selective NSAID.

Study design

First visit: at least 5 weeks before surgery.

Second visit: day of surgery.

Intervention

a. 4 weeks no treatment;

b. 4 weeks 2x daily 200 mg celecoxib/Celebrex until the surgery;

c. 4 weeks 2x daily 200 mg celecoxib/Celebrex until 3 days before surgery;

d. 4 weeks 3x daily 250 mg.
Naproxen/Aleve until 3 days before surgery.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with knee osteoarthritis eligible for and on the waiting list for total knee replacement surgery at the Sint Fransiscus Gasthuis hospital in Rotterdam.

Exclusion criteria

1. Patients who are eligible for a total knee replacement operation for other reasons than OA;

2. Patients with an increased risk for gastro-intestinal bleeding;

3. Patients with an increased risk of cardio-vascular disease such as a history of cardio-vascular disease like myocardium infarct, heart failure, CVA and TIA;

4. Patients with untreated/insufficiently treated hypertension;

5. Patients with angina pectoris and patients on oral anticoagulants;

6. Patients with serious liver and/or kidney function impairment;

7. Patients with intolerance for naproxen.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-12-2007
Enrollment:	172
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-12-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1510
NTR-old	NTR1579
Other	METC Rotterdam : 2007/36
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results