Disease modifying activity of celecoxib on articular cartilage in osteoarthritis.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25692

Bron
NTR

Verkorte titel
Disease modifying activity of celecoxib.

Aandoening

end stage knee osteoarthritis

Ondersteuning

Primaire sponsor: Sint Franciscus Gasthuis hospital Rotterdam
Overige ondersteuning: UMC Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

First visit: at least 5 weeks before surgery.

Second visit: day of surgery.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-12-2007
Aantal proefpersonen:	172
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-12-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten