

The direct effects of NSAIDS on osteoarthritic knee cartilage.

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Selective COX-2 inhibition is beneficial for matrix turnover.

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

Samenvatting

ID

NL-OMON21305

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

Osteoarthritis of the knee is a progressing degenerative joint disorder, characterised by joint pain and limitation of movement, leading to disability. Tissue changes comprise damage of joint cartilage, synovial inflammation and changes in subchondral bone, such as subchondral sclerosis and osteophyte formation (bony outgrowths).

Ondersteuning

Primaire sponsor: UMC Utrecht
Rheumatology & Clin. Immunology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference in proteoglycan release of osteoarthritic cartilage after treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Objectives:

Selective COX-2 inhibitors are prescribed for many disorders including osteoarthritis (OA), a degenerative joint disease with an incidence exceeding 10% of the adult population.

Recent in vitro studies showed a positive direct effect of celecoxib, one of the selective COX-2 inhibitors, on human OA cartilage. Such effects are difficult to verify in a clinical trial because changes in OA cartilage, degenerative and reparative, are slow and evaluation of articular cartilage by imaging techniques is still hampered by their limited sensitivity.

Therefore, an approach is used in which the benefits of in vivo treatment are combined with the benefits of ex vivo biochemical analyses of the cartilage.

Methods:

Patients with knee OA are treated 4 weeks prior to scheduled knee replacement surgery with celecoxib 2dd200mg, naproxen 3dd250mg, or indomethacin 2dd50mg. During surgery cartilage is collected and analyzed ex vivo.

Doel van het onderzoek

Selective COX-2 inhibition is beneficial for matrix turnover.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Celecoxib: 4 weeks, 2 times per day, 200 mg;

Naproxen: 4 weeks, 3 times per day, 250 mg;

Indomethacin: 4 weeks, 2 times per day, 50 mg.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with knee osteoarthritis according to the ACR criteria, considered for total knee replacement surgery.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Total knee replacement for other reason than osteoarthritis;
2. History of gastro-intestinal bleedings or perforation;
3. Increased risk for cardiovascular diseases (cardiovascular diseases in history, patients with untreated hypertension, patients with angina pectoris, and patients on oral anticoagulantia).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2004
Aantal proefpersonen:	42
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	29-08-2005
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	NL126
NTR-old	NTR159
Ander register	: N/A
ISRCTN	ISRCTN90366351

Resultaten

Samenvatting resultaten

Arthritis Res Ther. 2006;8(1):R2.