The direct effects of NSAIDS on osteoarthritic knee cartilage.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21305

Source
NTR

Brief title
N/A

Health condition

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).

Sponsors and support

Primary sponsor: UMC Utrecht
Rheumatology & Clin. Immunology

Intervention

Outcome measures

Primary outcome

Difference in proteoglycan release of osteoarthritic cartilage after treatment.

Secondary outcome

ProsteoglandinE2 levels produced by cartilage.

Study description

Background summary

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.

Study objective

Selective COX-2 inhibition is beneficial for matrix turnover.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2004
Enrollment:	42
Type:	Actual

Ethics review

Positive opinion

Date:	29-08-2005
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	NL126
NTR-old	NTR159
Other	: N/A
ISRCTN	ISRCTN90366351

Study results

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