ISRCTN90366351 https://doi.org/10.1186/ISRCTN90366351

The direct effects of non-steroidal anti-inflammatory drugs (NSAIDS) on osteoarthritic knee cartilage

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/05/2009	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR159

Study information

Scientific Title
Selective COX-2 inhibition is beneficial for matrix turnover: a clinical study

Study objectives
Selective COX-2 inhibition is beneficial for matrix turnover.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
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

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Celecoxib, naproxen, indomethacin

Primary outcome measure
Difference in proteoglycan release of osteoarthritic cartilage after treatment

Secondary outcome measures
Prosteoglandin E2 levels produced by cartilage

Overall study start date
01/11/2004

Completion date
01/12/2005

Eligibility

Key inclusion criteria
Patients with knee osteoarthritis according to the American College of Rheumatology (ACR) criteria, considered for total knee replacement surgery.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
42

Key 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 anticoagulants)

Date of first enrolment
01/11/2004

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre

UMC Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details
PO Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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