Effectiveness of Diclofenac versus Paracetamol in primary care patients with knee osteoarthritis.

No registrations found.

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

Summary

ID

NL-OMON21842

Source
NTR

Brief title
N/A

Health condition

Knee osteoarthritis, pain, General Practitioner, NSAID, Paracetamol

Sponsors and support

Primary sponsor: Erasmus MC, Department of general practice
Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Outcome measures

Primary outcome

Pain and function measured with the Knee Injury and Osteoarthritis Outcome Score (KOOS).

Secondary outcome

1. Patients' perceived pain measured on a 11 point numerical rating scale (NRS) (0= no pain; 10= unbearable pain).

2. Patients' quality of life using the EuroQol instrument EQ-5D.

3. All direct medical and patient costs (TIC-P Questionnaire) and indirect costs (PRODISQ).

4. Compliance to the therapy.

5. Co-interventions (e.g. changes in doses of co-medication).

6. Adverse reactions.

Study description

Background summary

Objectives:
Therefore, the primary objective is to assess whether
there is a clinically relevant effectiveness of Diclofenac compared to
Paracetamol over a period of two weeks and if necessarily another two
weeks in new consulters with knee OA in the general practice.

Study design:
A randomized open label trial.

Study population:
154 primary care patients of 45 years and older consulting their general practitioner with a complaints of pain due to knee OA.

Intervention:
One group of patients (N=77) receives Diclofenac
(maximum daily dose of 150 mg) and the other group (N=77) receives
Paracetamol (maximum daily dose of 3000 mg) for a period of two weeks
and if necessarily another two weeks.

Main outcomes:
The primary outcomes are pain and function measured with the Knee Injury and Osteoarthritis Outcome Score (KOOS).

Study objective

What is the effectiveness of Diclofenac compared to Paracetamol over a period of two weeks and if necessarily another two weeks (consistent with the Dutch guidelines for general practitioners) in new consulters with knee osteoarthritis in the general practice.

Study design

All outcome measures will be obtained by a questionnaire at baseline and at 3,6, 9, and 12 weeks after randomization, with the exception of the outcome measures pain on the 11-point NRS and therapy compliance that will be assessed daily through a diary. Costs will only be obtained at 12 weeks follow-up.

Intervention

Treatment with diclofenac (maximum daily dose of 150 mg) or Paracetamol (maximum daily dose of 3000 mg) for a period of two weeks and if necessarily another two weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients consulting for a new episode with non-traumatic knee pain in the general practice.

2. Complying to the clinical American College of Rheumatology (ACR) criteria for osteoarthrosis of the knee.

3. Have an indication for pain medication.

4. A score of 3 or more on the pain severity scale (0-10 scale).

5. Patients' aged 45 years or older.

Exclusion criteria

1. Contra-indication for NSAID or Paracetamol use (these are: Gastrointestinal bleedings in history or active, blood dyscrasia, bone marrow depression, serious heart failure, serious liver or kidney disease (glomerular filtration < 30 ml/min), known alcoholism, Colitis Ulcerosa, Crown disease, sulphite hypersensitivity, appearance of asthma, urticaria, angioedema, nasal polyps or rhinitis after use of acetylsalicylic acid or other prostaglandin synthetase inhibitors, or use of anti-depressives (SSRIs).

2. An arthroplasty or osteotomy of the knee in contralateral or unilateral side.

3. Already taking NSAID or Paracetamol medication of similar or higher doses as in the study.

4. Surgery or major trauma of the affected joint within the previous 6 months.

5. Pregnancy.

6. Use of corticosteroid of hyaluronic acid.

Study design

Design

Study type:	Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2009
Enrollment:	154
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-10-2008
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	NL1425

Register	ID
NTR-old	NTR1485
Other	- : 0801-38
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A