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

Gepubliceerd: 09-10-2008 Laatst bijgewerkt: 13-12-2022

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...

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

Samenvatting

ID

NL-OMON21842

Bron
NTR

Verkorte titel
N/A

Aandoening

Knee osteoarthritis, pain, General Practitioner, NSAID, Paracetamol

Ondersteuning

Primaire sponsor: Erasmus MC, Department of general practice
Overige ondersteuning: Fonds NutsOhra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Erasmus Medical Center
Department of General Practice
Room NA1905
PO Box 2040
P.A.J. Luijsterburg
Rotterdam 3000 CA
The Netherlands
+31 10 7037513

Wetenschappelijk

Erasmus Medical Center
Department of General Practice
Room NA1905
PO Box 2040
P.A.J. Luijsterburg
Rotterdam 3000 CA
The Netherlands
+31 10 7037513

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	154
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	09-10-2008
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	NL1425
NTR-old	NTR1485
Ander register	- : 0801-38
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A