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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33703

Source
ToetsingOnline

Brief title
DIPA-trial

Condition

- Other condition

Synonym
Knee osteoarthritis

Health condition

Aandoeningen van het bewegingsapparaat

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Fonds NutsOhra

Intervention

Keyword: General practice, Knee osteoarthritis, NSAID, Paracetamol

Outcome measures

Primary outcome

The primary outcomes are pain and function measured with the Western Ontario and McMaster (WOMAC) Osteoarthritis Index calculated with the Knee Osteoarthritis Outcome Score (KOOS) over a maximum follow-up period of 12 weeks.

Secondary outcome

Secondary outcomes are: 1) patients* perceived pain, 2) Perceive recovery, 3) patients* quality of life, 4) all direct and indirect medical and patients* costs, 5) compliance to therapy, 6) co-interventions, and 7) adverse reactions.

Study description

Background summary

Based on the lack of trials on comparative effectiveness of NSAIDs versus Paracetamol in patients consulting the general practitioner (GP) for a new episode of pain due to knee osteoarthritis (OA), we need to support the Dutch GP with sufficient knowledge for a convinced choice of type of initial pain medication. We should know if there is a clinically relevant difference between the medication and related additional costs.

Study objective

The primary objective is to assess whether there is a clinical relevant effectiveness of NSAID compared to Paracetamol over a period consistent with

the Dutch guidelines for general practitioners in new consulters with knee OA in general practice.
Secondary objectives are 1) to identify possible predefined predictors of a clinical relevant better effectiveness of Diclofenac versus Paracetamol over the treatment period and 2) when additionally funding is obtained, to assess the cost-effectiveness of Diclofenac compared to Paracetamol in new consulters with knee or hip OA in general practice.

Study design

A pragmatic randomized open label trial.

Intervention

One group of patients (n=77) receives Diclofenac (with a maximum daily dose of 150 mg, 3x50 mg) and the other group (n=77) receives Paracetamol (with a maximum daily dose of 3000 mg, 6x500 mg) for a period of two weeks and if necessarily another two weeks (conform the Dutch guidelines for general practitioners).

Study burden and risks

The burden of this study will be minimal because it will evaluate two medications (Diclofenac versus Paracetamol) that are already prescribed frequently in the targeted patient population, patients with knee OA. Subsequently, during the study, patients will fill in a questionnaire for five times, and assess their daily pain and compliance to the medication in a diary.
Because of lack of evidence to use the safer Paracetamol, the majority of patients with (knee) OA in primary care are prescribed NSAIDs to reduce pain, even if they consult their GP for the first time for pain due to knee OA. OA is the most frequent joint disease and is a chronic disease causing pain and disability of especially the knee. Therefore, we evaluate the two medications in patients with knee OA. Patients* risks are limited and the same as in usual daily GP care and described in the summary of product characteristics (SPCs) of involved medication and patients* information leaflets.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Complying to the clinical American College of Rheumatology (ACR) criteria for osteoarthrosis of the knee.
- Have an indication for pain medication.
- A score of 3 or more on the pain severity scale (0-10 scale).
- Patients* aged 45 years or older.

Exclusion criteria

- Contra-indication for NSAID or Paracetamol use
- An arthroplasty or osteotomy of the knee in contralateral or unilateral side.
- Already taking NSAID or paracetamol medication of similar or higher doses as in the study.
- Surgery or major trauma of the affected joint within the previous 6 months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2009
Enrollment:	154
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Diclofenac
Generic name:	Diclofenac
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Paracetamol
Generic name:	Paracetamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	01-12-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-04-2009

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-04-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2008-004114-28-NL
CCMO	NL25624.078.08
Other	NTC 1485