PACE Plus trial

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Low back pain is common and associated with a considerable burden to patients and society. There is uncertainty regarding the relative benefit of Paracetamol and Diclofenac and regarding the additional effect of pain medication compared with advice...

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

Samenvatting

ID

NL-OMON26717

Bron
NTR

Verkorte titel
PACE+

Aandoening

Acute low back pain

Ondersteuning

Primaire sponsor: Erasmus MC, department of General Practice
Overige ondersteuning: ZonMW (Dossier Number 80-83600-98-40003)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Low back pain intensity measured daily with an 11-point numerical scale (higher score means more pain).

Toelichting onderzoek

Achtergrond van het onderzoek

Primary Research Questions:

1. What is the effectiveness of advice plus paracetamol versus advice plus placebo regarding pain intensity over 4 weeks in patients with acute low back pain in general practice?

2. What is the effectiveness of advice plus diclofenac versus advice plus placebo regarding pain intensity over 4 weeks in patients with acute low back pain in general practice?

3. What is the effectiveness of advice plus paracetamol versus advice plus diclofenac regarding pain intensity over 4 weeks in patients with acute low back pain in general practice?

4. What is the effectiveness of advice plus paracetamol versus advice only regarding pain intensity over 4 weeks in patients with acute low back pain in general practice?

5. What is the effectiveness of advice plus diclofenac versus advice only regarding pain intensity over 4 weeks in patients with acute low back pain in general practice?

6. What is the effectiveness of advice plus placebo versus advice only regarding pain intensity over 4 weeks in patients with acute low back pain in general practice?

Study design: Multicenter, placebo-blinded, superiority randomized controlled trial using double dummy technique in primary care.

Study population: Patients (18 years and older) with acute non-specific low back pain presenting in general practice. Recruitment will take place in The Netherlands.

Interventions

Group 1: Advice (usual care conforming with the clinical guideline of the Dutch College of GPs)

Group 2: Advice (usual care conforming with the clinical guideline of the Dutch College of GPs) + paracetamol.

Group 3: Advice (usual care conforming with the clinical guideline of the Dutch College of GPs)+ diclofenac.

Group 4: Advice (usual care conforming with the clinical guideline of the Dutch College of GPs) + placebo.

All patients will be asked to continue taking the medicines (active or placebo) until they have experienced two consecutive days of pain rated 0 or 1 out of 10 on a numerical rating scale, or for a maximum of 4 weeks.

Main study parameters/endpoints: The primary outcome will be low back pain intensity measured daily over a 4 week follow-up period. Secondary outcomes will be disability, patient's perceived recovery, quality of life, cost-effectiveness, cost-utility, time to recovery, compliance to treatment, adverse reactions, patient satisfaction, sleep quality and use of co-interventions. These data will be captured at 2, 4 and 12 weeks follow-up.

After the first 3 months of insufficient patient recruitment, following discussions with participating GPs about the origin of the inclusion problems, the 'advice only' group was removed from the study design. Ethical approval for this design modification was obtained December 5th, 2016 from the Erasmus Medical Center Medical Research and Ethics Committee. Despite this design modification, no additional patients were included. For this reason, the PACE Plus trial was prematurely terminated on February 19th, 2017.
99 GPs from 40 general practice collaborated in the trial. During 6 months of recruitment, only 4 out of 31 referred patients could be included. Following the removal of the 'advice only' group from the design, 3 out of 4 included patients were lost to the trial.

Doel van het onderzoek

Low back pain is common and associated with a considerable burden to patients and society. There is uncertainty regarding the relative benefit of Paracetamol and Diclofenac and regarding the additional effect of pain medication compared with advice only in patients with acute low back pain. The objective of this study is to compare the short-term efficacy of these interventions.

Onderzoeksopzet

- Low back pain intensity (primary outcome measure) is recorded daily in a (digital) diary that patients will complete over a 4 week follow up period.

- Disability is measured at baseline and after 1, 2, 4 and 12 weeks of follow-up.

- Patients’ perceived recovery is measured after 2, 4 and 12 weeks of follow-up.

- Quality of life is measured after 4 and 12 weeks of follow-up.

- Costs are measured after 4 and 12 weeks of follow-up.

- Time to recovery will be assessed using the digital diary.

- Compliance to treatment is measured daily using the digital diary.

- Adverse reactions are recorded in the questionnaires after 2, 4 and 12 weeks of follow-up.

- Patients’ satisfaction is measured after 2, 4 and 12 weeks of follow-up.

- Sleep quality is measured at baseline and after 2, 4 and 12 weeks of follow up.

- Co-interventions are recorded after 2, 4 and 12 weeks of follow-up.

Onderzoeksproduct en/of interventie

Patients are randomly allocated to one of the four treatment groups using a concealed allocation procedure:

Group 1: Advice (usual care conforming with the clinical guideline of the Dutch College of GPs)

Group 2: Advice (usual care conforming with the clinical guideline of the Dutch College of GPs) + paracetamol 4 times daily, 1000 mg + 2 times placebo diclofenac

Group 3: Advice (usual care conforming with the clinical guideline of the Dutch College of GPs) + diclofenac 2 times daily, 75 mg + 4 times placebo paracetamol

Group 4: Advice (usual care conforming with the clinical guideline of the Dutch College of GPs) + placebo 4 times daily placebo paracetamol, 2 times placebo diclofenac

Since the dosage schemes of diclofenac and paracetamol differ, we make use of double dummies (i.e. placebo paracetamol and placebo diclofenac) in order to optimally blind patients, physicians and outcome assessment in groups 2, 3 and 4. All patients are asked to continue taking the medicines (active or placebo) until they have experienced two consecutive days of pain rated 0 or 1 out of 10 on a numerical rating scale, or for a maximum of 4 weeks.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Patients with acute non-specific low back pain presenting in general practice;

- Aged between 18 and 60 years;

- Low back pain of less than 6 weeks duration;

- Primary complaint of pain in the area between the 12th rib and buttock crease, with or without radiating leg pain;

- Experiencing a new episode of low back pain, preceded by a period of at least one month without low back pain;

- Low back pain severe enough to cause at least moderate pain (¡Ý 4 on 0-10 NRS).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Have known or suspected serious spinal pathology (e.g. metastatic, inflammatory or infective diseases of the spine, cauda equina syndrome, spinal fracture);

- Be currently taking recommended regular doses of analgesics, including paracetamol or diclofenac;

- Have had spinal surgery within the preceding 6 months;

- Have serious co-morbidities like severe rheumatoid arthritis, cardiac failure, diabetes preventing prescription of paracetamol (eg: liver or renal failure) or diclofenac (e.g. ulcus, gastro-intestinal problems); use of proton pump inhibitors before inclusion is not an exclusion criterium, as the patient is considered to be protected (patient will have to continue using this medication during use of study medication);

- Using cumarinederivate, clopidogrel, prasugrel, ticagrelor, acetylsalicylacidderivate, systemic glucocorticoïd, SSRI, venlafaxine, duloxetine, trazodon of spironolactone or other medications that may interact with paracetamol and/or diclofenac;

- Known intolerance for paracetamol and/or diclofenac;

- Being pregnant or planning to become pregnant during the treatment period.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-09-2016
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	NL5901
NTR-old	NTR6089
Ander register	EudraCT : 2015-003882-26

Resultaten