# PACE Plus trial

No registrations found.

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| **Ethical review** | Positive opinion |
| **Status** | Suspended |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26717

**Source**
Nationaal Trial Register

**Brief title**
PACE+

**Health condition**

Acute low back pain

### Sponsors and support

**Primary sponsor:** Erasmus MC, department of General Practice
**Source(s) of monetary or material Support:** ZonMW (Dossier Number 80-83600-98-40003)

### Intervention

### Outcome measures

#### Primary outcome

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

#### Secondary outcome

- Disability (Roland Morris Disability Questionnaire)

- Patients' perceived recovery (7-point Likert scale dichotomized into recovered (score 1 'complete recovery' and 2 'much improved) and not-recovered (score 3 'improvement' to score 7 'worse than ever'))

- Quality of life (EuroQol-5D)

- Costs (iMedical Consumption Questionnaire (iMCQ) and iProductivity Cost Questionnaire (iPCQ))

- Time to recovery (pain diary)

- Compliance to treatment (digital diary derived from the Brief Medication Questionnaire)

- Adverse reactions

- Patients' satisfaction (11-point numerical rating scale; higher score means more satisfaction).

- Sleep quality (4 point Likert scale derived from the Pittsburgh Sleep Quality Index (PSQI); scores dichotomized into good sleep quality (score 1 'very good' and 2 'fairly good') and poor sleep quality (score 3 'fairly bad' and 4 'very bad'))

- Co-interventions

# Study description

**Background summary**

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.

## Study objective

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.

## Study design

- 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.

## Intervention

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.

## Contacts

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## Eligibility criteria

## Inclusion criteria

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).

## Exclusion criteria

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.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |

## Recruitment

NL

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|---|---|
| Recruitment status: | Suspended |
| Start date (anticipated): | 01-09-2016 |
| Enrollment: | 800 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion

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|---|---|
| Date: | 14-09-2016 |
| 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 | NL5901 |
| NTR-old | NTR6089 |
| Other | EudraCT : 2015-003882-26 |

# Study results