# Step-down versus step-up analgesics in patients with (sub)acute sciatica in primary care.

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1. What is the effectiveness of immediate opioid pain medication (followed by step-down) versus step-up pain medication within the treatment according general practitioners' clinical guideline in patients with (sub)acute sciatica, over a period of 6...

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

## Samenvatting

### ID

NL-OMON26984

**Bron**
NTR

**Verkorte titel**
STEP-UP trial

**Aandoening**

Sciatica, Pain medication, Cost-effectiveness

### Ondersteuning

**Primaire sponsor:** Erasmus MC, Erasmus Medical Center Rotterdam, departement of General Practice
**Overige ondersteuning:** ZonMW, The Netherlands Organization for Health Research and Development

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Pain severity of the leg (11 point numerical rating scale; higher score means more pain) measured daily over a period of 6 weeks follow-up.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale:

A systematic review and meta-analysis (2012) reported that the efficacy and tolerability of pain medication commonly prescribed for the management of sciatica in primary care is unclear. There are no data available about the (cost)-effectiveness regarding the recommended stepped medication care in patients with sciatica.

Objective:

What is the effectiveness and cost-effectiveness of immediate opioid pain medication (followed by step-down) versus step-up pain medication within the treatment according general practitioners' clinical guideline in patients with (sub) acute sciatica, over a period of 6 and 12 weeks respectively?

Study design:

A randomized controlled trial with alongside an economic evaluation.

Study population:

Patients aged 18 to 65 years (n=234) who are consulting their general practitioner with (sub)acute sciatica with a pain severity of 7 or more on an 11-point numeric rating scale.

Intervention:

Patients will be randomized in two groups: 1) receiving immediate morphine; followed by a taper period (step-down), and 2) receiving stepped-up medication (step1: paracetamol, step2: NSAID, step3: tramadol, step4: morphine).

Main study parameters/endpoints:

The primary outcome is severity of leg pain. Secondary outcomes are adverse reactions, costs, quality of life, patients' perceived recovery, patients' perceived comfort during tapering of the medication, disability, pain severity of the low back, number of days with a severity of leg pain score of 7 or more, compliance to treatment, use of 'rescue medication', patients' satisfaction, and co-interventions.
Outcomes will be measured at baseline and at 3,6,9,12 weeks follow-up.

**Doel van het onderzoek**

1. What is the effectiveness of immediate opioid pain medication (followed by step-down) versus step-up pain medication within the treatment according general practitioners' clinical guideline in patients with (sub)acute sciatica, over a period of 6 weeks?
2. What is the cost-effectiveness of immediate opioid pain medication (followed by step-down) versus step-up pain medication within the treatment according general practitioners' clinical guideline in patients with (sub)acute sciatica, over a period of 12 weeks?

**Onderzoeksopzet**

All participating patients will fill in the questionnaires at baseline and at 3,6, 9, 12 weeks. During the first 6 weeks the patients will be fill in an online diary.

**Onderzoeksproduct en/of interventie**

Group 1: Step-down: Immediate Morphine, with tapering period.

Group 2: Step-up: First Paracetamol, Second NSAID, Thrith Tramadol, Fourth Morphine. (according general practitioners' clinical guideline).

# Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients will be eligible for inclusion if they:

1. Are aged 18 to 65 years

2. Don’t use opioids

3. Have radiating (pain) complaints in one leg below the knee

4. Have a severity of pain scored 7 or more on an 11-point numerical rating scale (0= no pain; 10= maximum pain)

5. Have less than 12 weeks (pain) complaints

6. Have at least one of the following symptoms:

- More pain on coughing, sneezing or straining

- Decreased muscle strength in the leg

- Sensory deficits in the leg

- Decreased reflex activity in the leg

- Positive straight leg raising test.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

1. An episode of radiating (pain) complaints occurred in the preceding 6 months

2. Back surgery in the past 3 years

3. Treated with epidural injections

4. Pregnancy

5. Co-morbidity that primary determines overall wellbeing such as an osteoporotic fracture, malignity, herpes zoster and Lymes'disease

6. Hypersensitivity to paracetamol, NSAID or opioids

7. Previous or active peptic ulcer

8. Direct indication for surgery (fast progression of paresis or cauda equina syndrome

9. History of substance addiction or abuse.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving tijdelijk gestopt |
| (Verwachte) startdatum: | 13-04-2015 |
| Aantal proefpersonen: | 234 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 26-03-2015 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44314
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL4883 |
| NTR-old | NTR5120 |
| CCMO | NL49507.078.14 |
| OMON | NL-OMON44314 |

# Resultaten

### Samenvatting resultaten

NA