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

Published: 27-08-2014
Last updated: 15-05-2024

Primary Objective: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,...

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

Summary

ID

NL-OMON44314

Source
ToetsingOnline

Brief title
Step-up trial

Condition

- Joint disorders
- Spinal cord and nerve root disorders

Synonym
Sciatica

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW Goed Gebruik Geneesmiddelen

Intervention

Keyword: general practice, NSAID, opiod, paracetamol, sciatica

Outcome measures

Primary outcome

The primary outcomes are severity of leg pain.

Outcomes will be measured at baseline and at 3,6,9,12 weeks and 1 and 2 years follow-up.

Secondary outcome

Secundary outcomes are adverse reactions, costs, quality of life, patients* perceived recovery, Patients* perceived comfort during tapering of the medication, disability, severity of low back pain, number of days with a severity of leg pain score of 7 or more, compliance to treatment, use of *rescue medication*, patients* satisfactionand co-interventions.

Outcomes will be measured at baseline and at 3,6,9,12 weeks and 1 and 2 years follow-up.

Study description

Background summary

Sciatica is the most prevalent specific cause of low back disorders seen by general practitioners. The treatment of patients with sciatica is for a large part aimed to stay active and return to daily activities. In order to facilitate this aim, but also as a purpose on its own pain relieve due to adequate analgesic(s) prescription is an important condition. There are two prescription strategies to relieve pain: A) immediate opioid pain medication, followed by a step-down approach, and B) step-up which means first paracetamol, if necessary than a NSAID and hereafter an opioid.

There are no data available about the (cost)-effectiveness regarding the

recommended stepped medication care in patients with sciatica.
Return to work is the most dominating factor within the total costs in sciatica. The (cost)effectiveness of the step-down versus step-up medication will depend on the magnitude to patients* health gain, the proportion of patients returning to work and the time-period needed for returning to work. Our study will assess the (cost)-effectiveness of the prescription strategy of direct opioid prescription (step-down) as seen in daily practice compared with pain medication by the general practitioner as described in the clinical NHG guideline (step-up).

Study objective

Primary Objective:
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?

Secondary Objective(s):
1) 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?
2) What is the course and medical consumption (including surgery) during 2 years follow-up?
3) What are effectmodifiers for effectiveness in the two prescription strategies for pain relieve?

Study design

A pragmatic randomized controlled trial with parallel group design, in general practice with a 2 year follow-up period.

Intervention

Patients will be randomized in two groups: A) receiving directly morphine; followed by a taper period (step-down, and B) receiving stepped-up medication (Step1: paracetamol, Step2: NSAID, Step 3: tramadol, Step 4: morphine).

Study burden and risks

The burden will be minimal because the trial evaluates medications that are already prescribed frequently in patients with sciatica. Besides that, the allocated medication strategies are prescribed conform the Dutch clinical guidelines of the general practitioners. A rather small burden for the patients is that they have to fill in 7 questionnaires in a period of 2 years, and

assess their daily pain and compliance to prescribed medication in a diary during the first 3 months.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Women and men aged 18 to 65 years,
2) No use of analgesics besides paracetamol,
3) Radiating (pain) complaints in one leg below the knee,
4) Severity of pain scored 7 or more on an 11-point numerical rating scale (0<= no pain; 10<= maximum pain),
5) Duration of the (pain) complaints less than 12 weeks,
6) Presence of at least one of the following symptoms: a) More pain on coughing, sneezing or straining, b) Decreased muscle strength in the leg, c) Sensory deficits in the leg, d)

Decreased reflex activity in the leg, e) Positive straight leg raising test

Exclusion criteria

1) An episode of radiating (pain) complaints 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 osteoporostic 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.

Study design

Design

Study phase:	4
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):	23-04-2015
Enrollment:	234
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Morphine
Generic name:	morphine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	NSAID: diclofenac
Generic name:	diclofenac
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Paracetamol
Generic name:	paracetamol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tramadol
Generic name:	tramadol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-08-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-04-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-08-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-12-2015

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-03-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-04-2016
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

ID: 26984
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2014-002177-11-NL
CCMO	NL49507.078.14
Other	NTR
OMON	NL-OMON26984