Cost-effectivenes of minimal interventional procedures for patients with chronic low back pain.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20202

Source
NTR

Brief title
MinT-study

Health condition

Patients with mechanical low back pain who are referred by a general practitioner or medical specialist to participating pain clinics.

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Pain intensity after 3 months.

Secondary outcome

1. Global perceived recovery;

2. Quality of life;

3. Patient satisfaction;

4. Functional status;

5. General health;

6. Chronic pain experience.

Study description

Background summary

Background:

Minimal interventional procedures are frequently applied in patients with back pain resulting from single sources: facet, discus, sacroiliac joint or a combination of these (defined as mechanical low back pain). These minimal interventional procedures are an integral part of a multidisciplinary pain program. A recent systematic review issued by the Dutch Health Insurance Council showed that the effectiveness of these procedures for the total group of patients with chronic low back pain is unclear and cost-effectiveness unknown. To provide this missing evidence, the aim of the study is to evaluate whether a multidisciplinary pain program with minimal interventional procedures is cost-effective compared to the multidisciplinary pain program alone for patients with chronic mechanical low back pain who did not respond to conservative primary care and were referred to a pain clinic.

Methods:

All patients with chronic low back pain who are referred to one of the 13 participating pain clinics will be asked to participate in an observational study. Patients with a suspected diagnosis of facet, discus or sacroiliac joint problems will receive a diagnostic test to confirm these problems. If positive, they will be asked to participate in a Randomized Controlled Trial (RCT). Hence, for each single source a separate RCT will be conducted. Patients with a combination of facet, discus or sacroiliac joint problems will be invited for participation in a RCT as well. An economic evaluation from a societal perspective will be performed alongside these four RCTs. Outcome measures are pain intensity, recovery, functional status, general health, patient satisfaction, chronic pain experience and costs. Patients will complete

questionnaires at baseline, 3 and 6 weeks, 3, 6, 9 and 12 months after randomisation. Costs will be assessed using monthly cost diaries.

Results:

Currently, the study is approved by the Medical Ethics Research Committee, and the pain clinics and physiotherapists are being recruited. Inclusion of patients will most probably start in September 2012. There are no results available yet. Final results will be expected in 2015.

Conclusions:

No trials are yet available which have evaluated the cost-effectiveness of minimal interventional procedures in patients with chronic mechanical low back pain, which emphasizes the importance of this study. The Dutch Ministry of Health will use the results of this study to decide whether or not minimal interventional procedures for chronic mechanical low back pain should be reimbursed within the Dutch public health insurance.

Study objective

Chronic low back pain is a common complaint associated with high costs. Minimal interventional procedures are frequently applied in pain clinics in patients with pain resulting from the facet, disc, sacroiliac joint or a combination of these kind of complaints. A recent systematic review showed that the effectiveness of minimal interventional procedures for the total group of chronic low back pain patients is unclear and the cost-efectiveness unknown. The aim of this study is to evaluate whether a multidisciplinary pain programme with minimal interventional procedures is effective and cost-effective compared with the multidisciplinary pain programme alone for patients with mechanical low back pain who did not respond to conservative primary care and were referred to a pain clinic.

Study design

Pain intensity, Global perceived recovery and quality of life will be measured at baseline, 3 weeks, 6 weeks, 6 months, 9 months and 12 months.

Patients satisfaction, functional status, general health and chronic pain experience will be measured at baseline 3 months, 6 months, 9 months and 12 months.

Intervention

Interventiongroup:

1. Facet join pain: Radiofrequency denervation of the ramus dorsalis at L3, L4, L5, S1 and the multidisciplinary pain programme (consisting of an exercise program and a psychologist visit if necessary);

2. Disc pain: Radiofrequency denervation of the involved discus and the multidisciplinary pain programme (consisting of an exercise program and a psychologist visit if necessary);

3. Sacroiliac join pain:Radiofrequency denervation of the ramus dorsalis at L5/S1, S2, S3, S4 and the multidisciplinary pain programme (consisting of an exercise program and a psychologist visit if necessary);

4. Patients with a combination of the single entities will be randomised after the clinical diagnosis to a group who receives minimal interventional treatments (i.e. a combination of the interventions mentioned above) and the multidisciplinary pain programme (consisting of an exercise program and a psychologist visit if necessary).

Duration and intensity of exercise programme:

The exercise program has a duration of three months with one or two physiotherapy treatments a week (the exact amount of physiotherapy treatments is patient specific).

Duration and intensity of psychologist visit:

No duration or intensity of the psychologist visits in this programma are specified. The anesthesiologist can refer the patient to the psychologist according to the results of the psychological questionnaires (and it is not a mandatory part of the multidisciplinary pain programme). This is usual care, and measured in the cost-questionnaires.

Control group:

Only the multidisciplinary pain programme (consisting of an exercise program and a psychologist visit if necessary).

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Eligibility criteria

Inclusion criteria

1. Chronic (more than 3 months) mechanical low back pain symptoms;

2. Age between 18 and 70 years;

3. No improvement of symptoms after at least three months of conservative treatment according to the Dutch guidelines for non-specific low back pain in primary care;

4. Patients must answer 'yes' on the question 'is there a 50% or more reduction in pain?', 30 minutes after the test block, or the disc provocation test must be positive.

Exclusion criteria

1. Patients with severe psychiatric or severe psychological problems;

2. Pregnant women;

3. Patients who are not able to complete the questionnaires;

4. Anticoagulant drug therapy and/or disturbed coagulation;

5. Patients with less than 50% reduction in pain after the test block, or a negative disc provocation test.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2012
Enrollment:	816
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-07-2012
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	NL3382

Register	ID
NTR-old	NTR3531
Other	ZonMW : 171202013
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A