Study on the effect of pain medication on functional capacity and self reported disability in patients with chronic low back pain;
a triple blinded RCT

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This study aims to investigate the effect of analgetics on a functional capacity evaluation (FCE) and self reported disability in patients with CLBP.

Ethical review	Approved WMO
Status	Pending
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32166

Source
ToetsingOnline

Brief title
Pain medication and functional capacity in chronic low back pain

Condition

- Musculoskeletal and connective tissue disorders NEC

Synonym
benign low back pain; chronic low back pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Grunenthal,Stichting Beatrixoord

Intervention

Keyword: chronic low back pain, functional capacity, pain medication, self reported disability

Outcome measures

Primary outcome

Primary outcome measure:

1. To assess limitations in work related activities specific for low back pain, subtests from the Work Well Functional Capacity Evaluation (FCE) will be used: lifting low, long carry two handed, static forward bend test loaded, and dynamic bending (Table pp 7 and appendix 6). A hand grip strength test is added as a non-CLBP related performance test to control for non-CLBP related pain behaviours.

2. RMDQ: Roland Morris Disability Questionnaire (described in *measures T1*, pp 6).

Secondary outcome

1.Control for compliance and side effects:

Three questions about compliance; one question about the dosage of the medication; open question for side effects of medication and FCE. Count remaining capsules/strips

2. Control for possible effect of mediators:

VAS-score for pain, pain relief (complete, important, moderate, slight, none or worse), SCL-90-R for distress, Tampa for fear, UCL for coping-strategy and PCL for pain-cognitions, CPAQ for acceptance, hand-grip test for pain behaviors (pp 6 and 7).

Study description

Background summary

Background
Disability resulting from non-specific chronic low back pain (CLBP) continues to be a large problem in western societies. According to the bio-psycho-social model, patient's functioning is influenced by biomedical, psychological and social factors. One of the factors is pain. Pain may lead to sensitization of pain modulating systems and this sensitization may lead to ongoing of the perception of pain in the absence of actual tissue damage; the pain becomes chronic. Chronic pain decreases functional capacity and increases disability of patients with CLBP. In many cases analgetics are prescribed to strive for reduction of pain and disability, improvement of functional capacity and return to work. It is still unknown what role analgetics will have on the actual performance and disability of the patient. The proposed study will shed light on the effect of analgetics on reduction of disability in patients with CLBP.

Study objective

This study aims to investigate the effect of analgetics on a functional capacity evaluation (FCE) and self reported disability in patients with CLBP.

Study design

Randomized Placebo-Controlled Clinical Trial.

Intervention

1. Wash-out of pain medication in one week
2. Study starts with measures T1.
3. Than treatment starts which consists of paracetamol/tramadol 325 mg/37.5 mg per capsule, or placebo. The dose will be titrated to maximally paracetamol 1950 mg; tramadol 225 mg; placebo in an identical way (maximally three times two capsules a day).
4.Two weeks after start medication, measures T2 take place.

5.After that medication (analgesic or placebo) will stop.
Control for compliance and side effects will take place.

Study burden and risks

Side effects
1. Tramadol has a number of potential side effects of which the subjects will be informed prior to enrollment. Side effects will also be tracked throughout the study.
The potential side effects are:
- Very often (>10%): nausea, dizziness;
- Often (1-10%): constipation, vomiting, dry mouth, sweating, confusedness, and headache;
- Sometimes (0.1-1%): dyspepsia, retching, palpitations, tachycardia, tiredness, itching, urticaria, orthostatic hypotension, cardiovascular deregulation.
- Rare (0.01-0.1): vision problems, psychological reactions, tremor, paresthesies, anorexia, miction problems, muscle weakness.
- Very rare (<0.01%): convulsions, bradycardia, allergic reactions, anaphylaxia, liverfunction problems, and depression of ventilation.
In a prior study however no serious adverse effects due to tramadol were observed (Ruoff, 2003). In former studies discontinuation of the treatment due to adverse effects was found in about 20% of the patients (Schnitzer, 2000; Ruoff, 2003).

2. Paracetamol seldom has side effects. These concern allergic reactions. Other adverse effects (for example liver problems) only occur in much higher doses than used in this study, or with longer use.

3.The FCE has been proven to be safe for patients with chronic low back pain. It can lead to a temporary increase in symptom intensity, but in a former study symptoms always returned to pre-FCE level.

Contacts

Public
Universitair Medisch Centrum Groningen

Dilgtweg 5
9751 ND, Haren
Nederland
Scientific

Universitair Medisch Centrum Groningen

Dilgtweg 5
9751 ND, Haren
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Non-specific low back pain with a VAS score >= 40mm, pain lasting longer than 3 months, age older than 18 years, and motivated for multidisciplinary rehabilitation. Patients are informed about the study and have signed informed consent form.

Exclusion criteria

Mental (for example major psychiatric disorders) or physical causes (for example cardiac or pulmonary problems) for reduction in functioning; hypertension; unable/unsafe to participate in Functional Capacity Evaluation (FCE); contra-indication for use of prescribed medication (use of MAO inhibitors, use of SSRI*s, known liver and renal function problems, epilepsy, brain damage, COPD, pregnancy); use of opioids; not willing to stop other treatments for CLBP (physiotherapy, manual therapy etc.). Patients will also be excluded if they had previously discontinued paracetamol/tramadol therapy due to adverse effects.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	zaldiar
Generic name:	acetaminophen/tramadol 325 mg/37.5 mg per capsule
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2008-004227-39-NL
CCMO	NL22301.042.08