A randomized, double blind, placebo-controlled study on the effect of 3 months treatment with the analgesic tapentadol on conditioned pain modulation (CPM) and pain relief in patients with chronic low back pain

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(1) To phenotype chronic low back pain patients in terms of endogenous modulation of pain, central sensitization/facilitation, and the presence of a neuropathic pain component;(2) To assess the effect of a three-month treatment with tapentadol on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON42741

Source
ToetsingOnline

Brief title
LCAT

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
low back pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Grunenthal,Leids Universitair Medisch Centrum

Intervention

Keyword: low back pain, tapentadol

Outcome measures

Primary outcome

Pain relief and change in endogenous pain modulation

Secondary outcome

Change in mood. daily activity and neuropathic pain cmplaints

Study description

Background summary

The current study has two parts. In part 1 we will phenotype the patients in terms of
(#1) Conditioned pain modulation
(#2) Offset analgesia
(#3) Temporal summation
(#4) Roland Morris Disability Questionairre which examines effects of LBP on activities of daily living
(#5) Neuropathic pain symptoms using PainDetect and Neuropathic Pain Symptom Inventory (NPSI) questionnaires*
(#6) Mood-related symptoms using Hopsital Anxiety and Depression Scale (HADS) and Profile of Mood States (POMS) questionnaires.

Phenotyping is done to get an indication of the baseline state of the patients in terms of endogenous pain modulation (#1 and 2), central sensitization/facilitation (#3), daily functioning (#4), the presence of a neuropathic pain component (#5) and mood disorders (#6).

Study objective

(1) To phenotype chronic low back pain patients in terms of endogenous modulation of pain, central sensitization/facilitation, and the presence of a neuropathic pain component;
(2) To assess the effect of a three-month treatment with tapentadol on pain relief and endogenous pain modulation in patients with chronic low back pain and defects in CPM;
(3) To assess whether specific factors derived from phenotypic baseline testing predict a response to tapentadol in fibromyalgia patients.

Study design

Double-blind, placeo controlled, randomized

Intervention

1. Pain tests for measurement of endogenous pain modulation
2. Questionnaires to assess mood, daily activity and neuropathic pain complaints
3. Treatment with tapentadol for 3 months

Study burden and risks

Some dizziness and constipation is possible in the first weeks of the study but we expect these complaints to dissipate witin weeks.
Benefit: Pain relief

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age: 18 - 75 years.;- Sex: Either sex.
- Inclusion criteria: American Society of Anesthesiologists class 1 and 2 patients, 18 - 75 years; BMI < 40 kg/m2, and ability to give informed consent. CLBP for > 3-months with a pain score of 3 or more on a numerical rating scale.
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Exclusion criteria

Unable to give written informed consent; medical disease such as pulmonary, renal, liver, cardiac, gastro-intestinal, vascular disease; (iii) allergy to study medication; (iv) history of illicit drug abuse or alcohol abuse; (v) history of psychosis; (vi) epilepsy; (vii) pregnancy and/or lactation; (viii) strong opioids and benzodiazepine use; (ix) previous extensive spinal surgery or spinal surgery in the past 6 months; (x) serious spinal pathology and (xi) diagnosed neurological disease.

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:	Recruitment stopped
Start date (anticipated):	04-10-2016
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Palexia
Generic name:	Tapentadol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	17-12-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-02-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2015-005259-28-NL
CCMO	NL55839.058.15

Study results

Date completed:	22-10-2018
Actual enrolment:	40