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 pain from fibromyalgia

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(1) To phenotype fibromyalgia patients in terms of endogenous modulation of pain, central sensitization/facilitation, the presence of a neuropathic pain component and small fiber neuropathy;(2) To assess the effect of a three-month treatment with…

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

Summary

ID

NL-OMON42796

Source
ToetsingOnline

Brief title
FCAT

Condition

- Muscle disorders

Synonym
chronic widespread 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: endogenous pain modulation, fibromyalgia, pain, tapentadol

Outcome measures

Primary outcome

Endogenous pain modulation (CPM) and pain relief by tapentadol vs placebo

Secondary outcome

Endogenous pain modulation (OA) and central sensitization

C-fiber morphology in the cornea

Effect of tapentadol on mood and neuropathic pain complaints

Study description

Background summary

The current study has two parts. In part 1 we will phenotype the patients in terms of
(#1) Endogenous pain modulation by measurement of conditioned pain modulation and offset analgesia;
(#2) Temporal summation (a measurement of central sensitization);
(#3) C-fiber density in the cornea;
(#4) Neuropathic pain symptoms using PainDetect and Neuropathic Pain Symptom Inventory (NPSI) questionnaires*
(#5) 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 modulation of pain (#1), central sensitization/facilitation (#2), the presence of a neuropathic pain component

(#3 and #4) and mood disorders (#5).

Item #1 will be used as inclusion criterion and only patients with absent CPM will be included in the study. Items #2-#5 will not be used as in- or exclusion criteria but they (excl. test #3) will be followed over time during treatment (at 1 month intervals) to assess the effect of tapentadol (relative to placebo) on the biomarkers of chronic pain.

In part 2, patients will be treated with tapentadol sustained relief tablets. They will ingest the medication twice daily for 3 months time. An initial titration phase of 3 weeks will be followed by 9 weeks of treatment. Patients will be contacted weekly by phone to report pain scores, and will visit the clinic monthly to perform test #1-#5 (excl. test #3). Offset analgesia will be tested only at baseline and after 3 months of treatment with tapentadol/placebo. Finally, all patients will be tested for CPM and offset analgesia (#1), temporal summation (#2) and questionnaires (#4 and #5) at a final visit, one month after termination of treatment.

Study objective

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

Study design

Double blind, randomized and placebo controlled

Intervention

1. 2 months oral treatent with tapentadol
2. Tests for endogenous pain modulation (CPM and OA) and central sensitization (Wind-up)
3. Cornea photos (to assess C-fiber morphology)
4. Questionanires to assess neuropathic pain complaints and mod.

Study burden and risks

Patients might experience some dizziness and constipation early on during treatment but it is expected that tehse complaints dissipate over time.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

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.
Additionally patients need to have a pain score * 5 (on a scale of 0-10) for most of the day and meet the 2010 American College of Rheumatology diagnostic criteria
-defects in CPM

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.

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):	11-03-2016
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 Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	22-02-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2015-005258-37-NL
CCMO	NL55837.058.15