The FCAT

No registrations found.

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

Summary

ID

NL-OMON28585

Source
NTR

Brief title
FCAT (Fibromyalgia, CPM, Analgesia, Tapentadol)

Health condition

Fibromyalgia

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

- Conditioned Pain Modulation (CPM)

- Temporal summation (TS)

- Offset Analgesia (OA)

- Pain relief

Secondary outcome

- Pain Detect questionnaire

- The Big Five Inventory

- Profile Of Mood States

- Neuropathic Pain Symptoms Inventory Questionnaire

- Hospital Anxiety and Depression Scale (HADS)

- C-fiber density in the cornea

Study description

Background summary

Patients will be phenotyped in term of endogenous pain modulation (CPM, OA), temporal summation, C-fiber density in the cornea, neuropathic pain symptoms and mood-related symptoms.

In case of an absent CPM a patients is included and randomized to receive either placebo or Tapentadol. Patients are treated for 3 months, they will visit the clinic monthly to preform tests (CPM, OA, TS, questionnaires), until one month after the medication is stopped.

Study objective

1. Tapentadol produces effective pain relief

2. Tapentadol treatment improves/enlarges CPM resonses

3. Tapentadol treatment improves/reduces temporal summation responses

4. Tapentadol treatment improves/reduces offset analgesia responses

5. Tapentadol is most efficacious in patients with initial defects in CPM and/or in patients that have a neuropathic pain component

Study design

Patients will be treated for 3 months. Once a month the will visit the hospital to test CPM, TS

and OA until one month after the medication is stopped.

Intervention

Patients will be treated with a placebo or Tapentadol for 3 months.

Contacts

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Eligibility criteria

Inclusion criteria

American Society of Anesthesiologists class 1 and 2 patients, 18 – 75 years; BMI < 40 kg/m2.

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. Patients need to have a absent/inactive CPM response.

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.

Patients are not allowed to continue co-analgesics that target CPM.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2016
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2016
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	NL5902
NTR-old	NTR6090
Other	LUMC : P15.361

Study results

Summary results
N/A