The FCAT

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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....

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28585

Bron
NTR

Verkorte titel
FCAT (Fibromyalgia, CPM, Analgesia, Tapentadol)

Aandoening

Fibromyalgia

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: Leiden University Medical Center (LUMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Conditioned Pain Modulation (CPM)
- Temporal summation (TS)
- Offset Analgesia (OA)

- Pain relief

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-09-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5902
NTR-old	NTR6090
Ander register	LUMC : P15.361

Resultaten

Samenvatting resultaten
N/A