The LCAT study

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1. Tapentadol produces effective pain relief in low back pain patients 2. Tapentadol treatment improves/enlarges CPM in patients with CPM defects 3. Tapentadol treatment improves/reduces temporal summation 4. Tapentadol is most efficacious in...

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

Samenvatting

ID

NL-OMON26947

Bron
NTR

Verkorte titel
LCAT (Low back pain, CPM, Analgesia, Tapentadol)

Aandoening

Low back pain

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 terms of endogenous pain modulation (CPM, Offset Analgesia), temporal summation, C-fiber density in the cornea, neuropathic pain symptoms and mood-related symptoms.

In case of an absent CPM patients are 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), one month after the treatment is stopped patients are tested one final time.

Doel van het onderzoek

1. Tapentadol produces effective pain relief in low back pain patients

2. Tapentadol treatment improves/enlarges CPM in patients with CPM defects

3. Tapentadol treatment improves/reduces temporal summation

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

Onderzoeksopzet

Patients are treated for 3 months. Before the start of the treatment and once a month during treatment patients will visit the hospital to test CPM, Temporal Summation and Offset Analgesia. One month after the treatment is stopped CPM, TS and OA are tested one final time.

Onderzoeksproduct en/of interventie

Patients are treated with a placebo or Tapentadol for 3 months.

Contactpersonen

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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, and ability to give informed consent. Chronic Low Back Pain for > 3-months with a pain score of 5 or more on a numerical rating scale ranging from 0 (= no pain) to 10 (= most extreme pain imaginable).

To be enrolled in the study, patients need to have an 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; (ix) previous extensive spinal surgery or spinal surgery in the past 6 months; (x) serious spinal pathology and (xi)

diagnosed neurological disease.

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:	04-10-2016
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-11-2016
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	NL6329
NTR-old	NTR6521
Ander register	LUMC : P15.362

Resultaten

Samenvatting resultaten
N/A