A Randomized, Double-blind, Placebo-controlled Trial on the Prevention of Chronic Postoperative Pain after Inguinal Hernia and Knee Surgery by Postoperative Treatment with Tapentadol

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

Samenvatting

ID

NL-OMON20334

Bron
NTR

Verkorte titel
PREVENT

Aandoening

Osteoarthritis, knee replacement surgery, inguinal hernia, inguinal hernia surgery.

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Leiden University Medical Center (LUMC), Grunenthal GmbH, Aachen Germany

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Both CPM and the presence of central sensitization (measured by TS and allodynia) will be measured before and after treatment to evaluate the effect of Tapentadol on these responses.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The development of chronic postoperative pain is not well understood. We recently conducted a large trial in patients who underwent inguinal hernia surgery and investigated whether the pre-operative state of the endogenous pain modulatory system (a central pain modulatory system important for normal pain perception) could predict the development of postoperative chronic pain after inguinal hernia surgery. In this study we demonstrated that a normal functioning endogenous pain modulatory system was predictive for the development of postoperative chronic pain. Tapentadol is an analgesic able to influence the endogenous pain system by maintaining its function and we hypothesize that treatment with tapentadol will reduce the change to develop postoperative chronic pain.
Objective: To prevent the development of chronic postoperative pain after inguinal hernia surgery and knee replacement surgery and to further explore the mechanism behind the development of chronic postoperative pain.
Study design: A double-blind, randomized, placebo-controlled, non-crossover longitudinal study.
Study population: Patients planned for elective inguinal hernia surgery or knee replacement surgery.
Intervention (if applicable): Postoperative treatment with oral tapentadol sustained release (maximum of 100 mg twice daily) and placebo.
Main study parameters/endpoints: (1) The effect of tapentadol compared to placebo on the development of chronic pain in the first year after surgery; (2) The influence of the pre-operative pain profile on the development of chronic postoperative pain and (3) The influence of tapentadol and placebo on the individual pain profiles and its influence on the development of chronic postoperative pain.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden for the patients is that they will take low doses of pain medication for 1 month after surgery and will come to the hospital 2 times for pain testing and questionnaires. The hospital visit will take about 30-45 minutes.

Doel van het onderzoek

We hypothesize that treatment with Tapentadol will reduce the development of chronic postoperative pain by enhancing or maintaining CPM responses and possibly reducing central sensitization. We hypothesize that a 4-week treatment with Tapentadol will reduce the risk for these patients to develop chronic postoperative pain in the first year after surgery.

Onderzoeksopzet

After the treatment period the development of chronic pain will be assessed by telephone at 3, 6 and 12 months after the surgery. Pain intensity will be assessed using the numerical rating scale (NRS) and patients will be asked to fill in a pain diary every month where they score the average pain score during rest and during exercise in the last month and last week.

Onderzoeksproduct en/of interventie

Tapentadol or placebo for a 4-week period

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients scheduled for elective inguinal hernia surgery(270) or knee replacement surgery

(270)
2. American Society of Anesthesiologists score 1, 2 or 3
3. Age between 18-80 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pain scores > 3 (on a 11-point numerical rating scale, NRS) reported for most of the day during the past month (except for knee pain in patients planned for knee replacement surgery);
2. Regular use of anti-depressants or anti-epileptics for any purpose, including SNRIs and gabapentinoids
3. Known allergies or contraindication to the study medication according to the SmPC
4. The presence of any chronic pain disorder (other than chronic knee pain);
5. Pregnancy/lactation;
6. Use of MAO-inhibitors or rifampicin within the last 14 days before inclusion;
7. Inability to perform psychophysical testing
8. Inability to give informed consent;
9. Inability to communicate with the investigators.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	540
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	27-01-2021
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	NL9223
Ander register	METC LDD : P20.084

Resultaten