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

No registrations found.

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

Summary

ID

NL-OMON20334

Source
NTR

Brief title
PREVENT

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC), Grunenthal GmbH, Aachen Germany

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. The effect of Tapentadol compared to placebo on acute postoperative pain in pa-tients planned for elective inguinal hernia surgery and knee replacement surgery.
2. The influence of the pre-operative pain profile (inhibitory as measured by CPM and facilitatory as measured by the presence of central sensitization) on the de-velopment of chronic postoperative pain in patients with and without chronic pain in the pre-operative phase.
3. The influence of Tapentadol and placebo on the individual pain profiles (inhibitory as measured by CPM and facilitatory as measured by the presence of central sensitization) and its influence on the development of chronic postoperative pain.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

Tapentadol or placebo for a 4-week period

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-03-2021
Enrollment:	540
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	27-01-2021
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	NL9223
Other	METC LDD : P20.084

Study results