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.

Published: 19-11-2019
Last updated: 30-01-2025

This study has been transitioned to CTIS with ID 2024-511010-21-00 check the CTIS register for the current data. To prevent the development of chronic postoperative pain after inguinal hernia surgery and knee replacement surgery and to to further...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52388

Source
ToetsingOnline

Brief title
Prevent

Condition

- Other condition

Synonym
Chronic pain

Health condition

Chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Grunenthal

Intervention

Keyword: Chronic postoperative pain, Tapentadol

Outcome measures

Primary outcome

The effect of tapentadol compared to placebo on the development of chronic pain in the first year after surgery

Secondary outcome

1. The effect of Tapentadol compared to placebo on acute postoperative pain in patients 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 development 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

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.

Study objective

This study has been transitioned to CTIS with ID 2024-511010-21-00 check the CTIS register for the current data.

To prevent the development of chronic postoperative pain after inguinal hernia surgery and knee replacement surgery and to to further explore the mechanism behind the development of chronic postoperative pain.

Study design

A double-blind, randomized, placebo-controlled, non-crossover longitudinal study.

Intervention

Postoperative treatment with oral tapentadol sustained release (maximum of 100 mg twice daily) and placebo.

Study burden and risks

The risk for the patients in the current study are minimal. Patients will be asked to use extra medication (outside the standard of care) for a period of 4 weeks. Most important side effects of the study medication are dizziness and somnolence. In case of unacceptable side effects the dose can be lowered during the study period.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients scheduled for elective inguinal hernia surgery or knee replacement surgery (to assess the severity of the knee osteoarthritis the Kellgren and Lawrance criteria will be used; see appendix 1).
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 (such as the presence of respiratory depression, severe astma, paralytic ileus and acute intoxications with alcohol, hypnotics or other psychotropic active substances); 4. The presence of any chronic pain disorder; 5. Pregnancy/lactation; 6. Use of MAO-inhibitors or rifampicin within the last 14 days before inclusion; 7. Inability to perform psychophysical testing (eg. in case of cognitive or psychiatric disorders); 8. Inability to give informed consent; 9. Inability to communicate with the investigators.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2020
Enrollment:	540
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Palexia
Generic name:	Tapentadol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-11-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-01-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
EU-CTR	CTIS2024-511010-21-00
EudraCT	EUCTR2018-004804-21-NL
CCMO	NL68622.058.18