The influence of pre-operative pain perception on the development on chronic pain after inguinal hernia repair surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28392

Source
Nationaal Trial Register

Brief title
PrePaIr-study

Health condition

Postoperative chronic pain after inguinal hernia repair surgery.

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center

Intervention

Outcome measures

Primary outcome

The primary outcome includes the development of chronic post-operative pain.

Secondary outcome

Secondary outcomes include:

1) Post-operative pain and analgesic consumption in the first 24 hours after surgery;

2) The effectiveness of the endogenous analgesic system (as measure for the nociceptive profile) in patients planned for elective inguinal hernia surgery.

Study description

Background summary

Postoperative pain and the development of chronic pain is a serious complication of surgical interventions. While the treatment of acute postoperative pain is well organized in current medical practice, the development of chronic pain still has a relatively large incidence. The latter depends on many factors including the type of surgery (a high incidence of postoperative chronic pain is observed following thoracotomies, mastectomies and inguinal hernia repairs) and specific patient-related factors. These patient-related factors include the state of the endogenous analgesia system, a modulatory and highly plastic system that is involved in modulation of afferent nociceptive input to central sites using top-down inhibitory and facilitatory pathways that inhibit or facilitate pain perception. The preoperative balance between anti- and pronociception may play a crucial role in the development of postoperative chronic pain. We believe that a diminished pain inhibitory system or an enhanced pain facilitatory system may enhance the risk to develop chronic postoperative pain. Some evidence for this comes from Yarnitsky et al. who showed that the ability to engage endogenous inhibitory pathways (as tested by the experimental paradigm of Conditioned Pain Modulation (CPM)) was associated with a lower risk of development of chronic post-thoractomy pain (odd ratio 0.52).1 In the current study we aim to pre-operatively test the effectiveness of the endogenous pain modulatory system (by conditioned pain modulation and temporal summation) in a large group of patients planned for an elective inguinal hernia repair.

Study objective

In the current study we aim to pre-operatively test the effectiveness of the endogenous pain modulatory system. We hypothesize that patients with a pre-operative anti-nociceptive profile (measured by CPM) will have a lower risk to develop chronic pain after surgery compared to patients with a pro-nociceptive profile (measured by temporal summation). Furthermore, we will use questionnaires to evaluate the psychological state of the patients, as it is known that patients with catastrophizing, anxious or depressive thought have a higher probability to develop chronic pain. We aim to correlate psychological parameters to the chance of developing chronic pain and to treatment effects.

We hypothesize that:

1) Patients with a pro-nociceptive profile will experience more pain direct post-operative, have a higher consumption of analgesics and have a higher probability of developing chronic post-operative pain compared to patients with anti-nociceptive profile.

2) Patients with catastrophizing, anxious or depressive thoughts have a higher probability to develop chronic pain and are more likely to have a pro-nociceptive profile.

Study design

1) The effectiveness of the endogenous analgesic system as measure for the nociceptive profile, will be tested 0-14 days prior to surgery.

2) The postoperative pain scores and analgesic consumption will be measured in the recovery room.

3) The development of chronic pain will be evaluated at 1,2,3,6 and 12 months after surgery.

Intervention

This study has no intervention. It is an observational study assessing the pre-operative nociceptive profile to study whether this is a predictive factor for the development of post-operative chronic pain.

Contacts

Public
Leiden University Medical Center

M. Niesters
Albinusdreef 2

Leiden 2333 ZA
The Netherlands
071-5262301
Scientific
Leiden University Medical Center

M. Niesters
Albinusdreef 2

Leiden 2333 ZA
The Netherlands
071-5262301

Eligibility criteria

Inclusion criteria

Inclusion criteria include:

1) American Society of Anesthesiologists score 1, 2 or 3;

2) age 18 to 75 year;

3) planned for elective inguinal hernia repair surgery (either open or laparoscopy).

Exclusion criteria

Exclusion criteria include:

(1) Pain scores > 3 (on a 11-point numerical rating scale, NRS) reported for most of the day during the past month;

(2) Regular use of analgesics for any purpose, including SNRIs, gabapentinoids, COX inhibitors or NSAIDs during the previous month;

(3) The presence of any chronic pain disorder;

(4) Inability to perform psychophysical testing (eg. in case of cognitive or psychiatric disorders);

(5) Inability to give informed consent;

(6) Inability to communicate with the investigators.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2015
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-07-2015
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	NL5188

Register	ID
NTR-old	NTR5336
Other	: P15-020

Study results

Summary results

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