The Influence of the Pre-operative Nociceptive Profile on the Development of Chronic Pain after Inguinal Hernia Repair Surgery

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44933

Source
ToetsingOnline

Brief title
The prepair studie

Condition

- Other condition

Synonym
chronic pain, neuropathic pain

Health condition

Pijngeneeskunde

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Wetenschapsfonds afdeling anesthesie (LUMC)

Intervention

Keyword: Chronic pain, Endogenous modulation of pain, Inguinal hernia

Outcome measures

Primary outcome

- endogenous pain modulation: pro-nociceptive profile vs anti-nociceptive

profile

- development of chronic pain

Secondary outcome

Acute pain and analgesic use in the first 24 hours after 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) 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 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 will have a lower risk to develop chronic pain after surgery compared to patients with a pro-nociceptive profile. 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.

Study design

This is a two-site, observational study. Patients will be operated by surgeons from the Leiden University Medical Center (LUMC) in Leiden or the Reinier de Graaf Groep (RdGG) in Delft.

In all patients the effectiveness of the endogenous analgesia system will be assessed 0-14 days before the surgery. An experienced experimenter will conduct the psychophysical assessment. The endogenous analgesia system will be evaluated using 2 separate psychophysical tests: 1) conditioned pain modulation, and 2) temporal summation. Both heat stimuli and electrical stimuli will be used. After surgery, we will record acute pain intensity and analgesic consumption during the first 24 hours. A monthly phone call for chronic post-operative pain and analgesic use will be pursued for 6 months. One year after surgery there will be a last assessment of pain (via telephone). For patients without chronic pain this is the study end. When patients do present them selves with chronic pain one year after surgery, we will invite these patients back in to the RdGG for one final assesment of the endogenous analgesia system.

Study burden and risks

The pain test may give redness and a burning sensation of the skin in the first 24 hours after the testing.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- American Society of Anesthesiologists score 1, 2 or 3
- aged 18 to 75 years
- planned to undergo elective surgery involving an inguinal hernia repair

Exclusion criteria

(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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2015
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	16-03-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	17-06-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	19-10-2017
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
CCMO	NL52238.058.15

Study results

Date completed:	30-01-2019
Actual enrolment:	250