

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

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| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving gestart                                     |
| <b>Type aandoening</b>      | -   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON28392

### Bron

NTR

### Verkorte titel

PrePaIr-study

### Aandoening

Postoperative chronic pain after inguinal hernia repair surgery.

### Ondersteuning

**Primaire sponsor:** Leiden University Medical Center

**Overige ondersteuning:** Leiden University Medical Center

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

## Toelichting onderzoek

### Achtergrond van het onderzoek

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).<sup>1</sup> 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.

### Doel van het onderzoek

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.

### **Onderzoeksopzet**

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.

### **Onderzoeksproduct en/of interventie**

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.

## **Contactpersonen**

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## Onderzoeksopzet

### Opzet

|                  |   |
|------------------|---|
| Type:            | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders  |
| Toewijzing:      | N.v.t. / één studie arm                             |
| Blinding:        | Open / niet geblindeerd                             |
| Controle:        | N.v.t. / onbekend                                   |

### Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 01-06-2015           |
| Aantal proefpersonen:   | 500                  |
| Type:                   | Verwachte startdatum |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 30-07-2015       |
| 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

NTR-new

NTR-old

Ander register

### ID

NL5188

NTR5336

: P15-020

## Resultaten

### Samenvatting resultaten

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