# Perioperative monitoring of inguinal hernia patients with a smartphone application, a pilot study

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON22945

**Source**
Nationaal Trial Register

**Brief title**
TBA

**Health condition**

Inguinal hernia

### Sponsors and support

**Primary sponsor:** na
**Source(s) of monetary or material Support:** BARD

### Intervention

### Outcome measures

**Primary outcome**

CPIP (chronic postoperative inguinal pain) 3 months post operative

**Secondary outcome**

Surgical site infection, return to work / daily activities

# Study description

### Background summary

Patient Reported Outcomes have become standard in the evaluation of inguinal hernia repair. However, the chosen outcomes remain heterogeneous, the measurements time-consuming or inadequate. Perioperative measurement of pain and recovery could benefit from the contemporary possibilities that mobile health applications offer.
An application for smartphones and tablets was developed using the twitch crowdsourcing concept, classical questionnaires, experiences from randomised clinical trials and patients' input.
Dichotomous questions and numeric rating scales, both pre- and postoperative, were implemented in the freely available Q1.6 application. Content, timing and frequencies were adapted to the inguinal hernia patient's daily life and assumed recovery. Certain combinations of answers were set as alert notifications to detect adverse events. Data is displayed on a web-based dashboard enabling real-time monitoring. Legal aspects were examined and taken into account.
The Q1.6 inguinal hernia app is an innovative tool for perioperative monitoring of pain and recovery of inguinal hernia patients. Previous limitations of classical measurements such as a large heterogeneity, retrospective data recording and different forms of bias can be eliminated. The `big data´ generated in this manner might be used for large-scale research to improve inguinal hernia surgery. A pilot study was performed to test the feasibility of the application and generated data even as the use in daily clinical practice for patients as well as physicians

### Study objective

Inguinal hernia application provides real-time monitoring. It also might provide more accurate, more reliable and more extensive data on recovery after surgery. Patients are questioned in a less intrusive way, leading to more compliance en less missing data or others forms of bias which are encountered with classical paper questionnaires

### Study design

Every day (postoperative day 1-14), every week (POD 15-90), every month (post operative month 4-12)

### Intervention

Pilot patients install the application prior to inguinal hernia surgery and are advised to use it 1 yr postoperatively

# Contacts

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# Eligibility criteria

## Inclusion criteria

Primairy inguinal hernia, adult, Dutch language, no cognitive impairment, in possession of smartphone or tablet with Android or iOS operating system

## Exclusion criteria

Previous inguinal (hernia) surgery, < 18 yr, insufficient language (Dutch) skills, cognitive impairment

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |

**Control:** N/A , unknown

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-09-2016 |
| Enrollment: | 250 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 19-05-2019 |
| 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 | NL7813 |
| Other | METC Brabant : NW2016-36 |

## Study results