Natural course of Pain following surgery through an Abdominal INcision: The Role of Adhesions and other factors in Chronification of abdominal pain

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal signs and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON49406

Source
ToetsingOnline

Brief title
Pain Trac

Condition

- Gastrointestinal signs and symptoms
- Gastrointestinal therapeutic procedures

Synonym
chronic pain, peritoneal adhesions

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW (veni grant: 91619035)

Intervention

Keyword: Adhesions, Chronic pain, Risk factors, Surgery

Outcome measures

Primary outcome

Main study outcome for phase one is the median and range of duration (days) of abdominal pain during rest and during daily activities following abdominal surgery.

Main outcomes for phase two is the percentage of patients with adhesions on cineMRI as compared between patients with and without chronic pain.

Secondary outcome

Secondary outcomes are predictive factors for development of pain, health-related quality of life, healthcare utilization, and return to daily activity or work. Predictors will be used to model a prediction model using regression techniques.

Secondary outcomes for phase 2 relate to the appearance of adhesions on cineMRI, and included extent and the loss of shear.

Study description

Background summary

Chronic abdominal and pelvic pain are highly prevalent in among patients who had abdominal surgery in history. An estimate of 11-20% of all patients undergoing different kinds of abdominal surgery will develop chronic abdominal

pain. Adhesions (a form of internal scar tissue) are the most common pathology found in patients undergoing diagnostic laparoscopy for pain. Other factors that might be associated with chronic post-operative pain are anxiety, depression, and female sex. Little is known about the natural course of pain after abdominal surgery, risk factors for developing chronic pain, and the mechanisms causing pain in patients with adhesions. In this longitudinal study we will prospectively study the natural course of pain through repeated measurements, and predictive factors for chronification of pain after different types of abdominal surgery.

Study objective

Primary objective is to elucidate the natural course of pain after abdominal surgery. Secondary objectives are assessment of risk factors for development of chronic pain after surgery, and comparison of adhesion formation between patient with and without development of chronic pain by mapping using cineMRI.

Study design

This is longitudinal prospective cohort study, including 1,500 patients scheduled for elective abdominal surgery. In phase one patients are asked to fill a comprehensive questionnaire, including quality of life assessment and a comprehensive assessment of potential predictive factors for chronic pain prior to surgery. Post-operatively pain symptoms will be monitored using short daily and weekly questionnaires taken by m-health and e-health techniques to study natural course of pain. A comprehensive assessment of pain, quality of life, and medical consumption will be taken at 3,6, and 12 months post-operatively. In phase two of the study patients who developed chronic pain will be invited for mapping of adhesions using cineMRI. Results of mapping of adhesions using cineMRI in patients with chronic abdominal pain will be compared to mapping of adhesions in 100 patients matched for type of surgery and risk factors who did not develop chronic pain.

Study burden and risks

In phase one of this cohort study patients will be asked to fill repeated questionnaires on pain and potential risk factors for chronic pain. The intake questionnaire prior to surgery will take approximately 60 minutes to fill. Post-operatively we will send short questionnaires that take 2-5 minutes to fill. These questionnaires will be send daily during the first 60 days after surgery and weekly afterwards. A more comprehensive questionnaire on abdominal pain and complaints that takes 45 minutes to complete will be send at 3,6, and 12 months post-operative. There are no risks related to participation in this study, nor are there direct benefits.

Patients participating in part two of this cohort will undergo cineMRI to

evaluate if pain symptoms might relate to adhesions form previous surgery. The MRI will take approximately 20 minutes to perform. MRI is a non-invasive imaging technique without health risks. However, there is a risk of incidental findings that do not relate to the subject of this study (adhesion formation). Patients who do not want to be informed about incidental findings will be excluded from phase two. In a subset female patients who had pelvic surgery and no resection of the uterus an additional transvaginal ultrasound will be made. Like MRI, this is a non-invasive diagnostic test without health risks. There is some additional inconvenience by the use of a transvaginal ultrasound prove. The test will take approximately 15 min.

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

Phase 1, initial inclusion:
- Adult patients, 18 years
- scheduled for elective abdominal surgery (e.g. laparotomy or laparoscopy), In phase 2 of the study (cineMRI) we will select a subgroup of the original cohort meeting these additional criteria:
- Chronic pain at 12 months post-operative as defined by International Association for Study of Pain (IASP) criteria:
- Daily pain in the past three months
- Pain is continues or intermittent
- Pain scores for the worst pain are 4 or higher
- patient has developed abdominal pain related to the surgical procedure
OR
- patients without chronic pain who are matched for type of surgery and risk factors for developing chronic pain.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Mental incompetence
- Planned for laparoscopic cholecystectomy
- Planned for Caesarean section, Additional exclusion criteria for phase two are:
- Contra-indications for MRI (without contrast) including:
- Severe claustrophobia
- Metal splinters in eyes
- Cerebral vascular clips
- Electronic medical implants
- Patient who does not want to be informed about potential incidental findings of MRI-scan

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-02-2021
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO Date:	25-07-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-01-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-06-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-11-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	30-07-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL68853.091.19