SELECT: New Silver or ancient gold? The new OnQ Silver soaker catheter versus the thoracic Epidural, the ancient golden standard in ERAS Colorectal surgery: a prospective superiority cohort study (Nederlandse titel: Nieuw silver of oud goud? De nieuwe „OnQ silver soaker katheter“ versus thoracale epiduraal, de oude gouden standaard in de darm chirurgie volgens het „early recovery after surgery ERAS“ programma, (het snel na een operatie weer herstellen).

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20161

Source
NTR

Brief title
SELECT

Health condition

postoperative pain after colorectal surgery
epidural analgesia
peripheral nerve block
abdominal wall block
pijn na darmoperatie
epiduraal
zenuwblokkade
buikwand blokkade

Sponsors and support

Primary sponsor: Wilhelmina Ziekenhuis Assen, The Netherlands
Source(s) of monetary or material Support: Wilhelmina Ziekenhuis Assen, The Netherlands

Intervention

Outcome measures

Primary outcome

The primary outcome objective of this trial will be length of stay in the hospital after surgery

Secondary outcome

intra- and postoperative opioid consumption

NRS pain scores

time in the post anesthetic care unit

time to mobilize to a sitting position in a chair

catheter dislocation

development of prolonged postoperative ileus

duration of bladder catheterization

overall patient satisfaction

Study description

Background summary

Rationale: Optimal recovery after colorectal surgery is also the main goal of all ERAS (early recovery after surgery) guidelines.

To fulfill the guideline and achieve this goal, a multidisciplinary approach of treatment is state of the art. An even more important point is: to create the possibility for all patients to start their postoperative adjuvant treatment as soon as possible after surgery. To reach this goal it is necessary to discharge the patients at the earliest possible after surgery, in the best possible condition.

The actual ERAS statement regarding intra- and postoperative analgesia recommends to not use thoracic epidural catheters in laparoscopic surgery anymore as a gold standard. This study will investigate an alternative possibility of pain therapy: delivering local anesthetic via a multi hole catheter to both sites of most surgical trauma - intra-abdominal as-well as preperitoneal.

Objective: The primary outcome objective of this trial will be length of stay in the hospital after surgery. Secondary outcome measures will be intra- and postoperative opioid consumption, NRS pain scores, time in the post anesthetic care unit, time to mobilize to a sitting position in a chair, catheter dislocation, development of prolonged postoperative ileus duration of bladder catheterization and overall patient satisfaction.

Study design: The study will be designed as a prospective cohort study. We will include 22 patients per cohort.

Study population: The study population will be drawn from al adult patients being eligible for right or left sided hemicolectomy, sigmoidectomy or low anterior rectum resection and matching the below named inclusion criteria. Both, benign and malign lesions will be included.

Intervention: The control group (cohort 1) will receive the standard treatment regimen with a thoracic epidural catheter (Ropivacaine 0,2% and Sufentanil 1mcg/ml). Depending on the type of surgery the epidural catheter will be used until POD 2 (hemicolectomy) or POD 3 (low anterior rectum resection). This resembles the hospital’s standard procedure.

The treatment group (cohort 2) will receive an intravenous Lidocaine 1% during the surgical procedure. At the end of surgery the surgeon will place two OnQ silver soaker multi hole catheters. Both catheters will be primed with a bolus of Ropivacaine 0,375% 10ml each and be then connected to an elastomeric pump (OnQ) filled with Ropivacaine 0,2% and will be used for 48 hours.

Main study parameter: length of stay in days

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Taking into account the result of a study on laparoscopic surgery in gynecology

we expect to see comparable little opioid use postoperatively, faster recovery with mobilization soon after surgery and a shorter length of stay in the interventional group.

Version number: 2.0 07-12-2018 !8 of 2! 9

These patients will be able to start their postoperative adjuvant treatment as soon as possible after surgery. To reach this goal it is necessary to discharge the patients at the earliest possible after surgery, in the best possible condition. With the standard care, an highly invasive procedure, the thoracic epidural we see a length of stay of about 6 days. With the less invasive intervention under investigation here we expect to see a shorter length of stay.

Study objective

The actual ERAS statement regarding intra- and postoperative analgesia recommends to not use thoracic epidural catheters in laparoscopic surgery anymore as a gold standard. This cohort study will investigate an alternative possibility of pain therapy: delivering local anesthetic via a multi hole catheter to both sites of most surgical trauma - intra-abdominal as-well as preperitoneal.

Taking into account the result of a study on laparoscopic surgery in gynaecology we expect to see comparable little opioid use postoperatively, faster recovery with mobilization soon after surgery and thereby a shorter length of stay in the interventional group.

Study design

primary outcome: measured from leaving the recovery area until discharge

Intervention

cohort 1: standard thoracic epidural

cohort 2: continuos abdominal wall block with catheter
preperitoneal and 2nd catheter intra-abdominal

Contacts

Public
C.A. Abusaris
Europaweg-Zuid 1
Assen 9400 RA
The Netherlands
Scientific
C.A. Abusaris

Europaweg-Zuid 1
Assen 9400 RA
The Netherlands

Eligibility criteria

Inclusion criteria

ASA 1-3

benign or malign indication for laparoscopic right/ left sided hemicolectomy, sigmoidectomy or low anterior rectum resection

> 18 years

informed consent (cohort 1 only for using outcome data, cohort 2 also for the actual intervention)

Exclusion criteria

ASA 4 or higher

chronic pain

chronic use of opioids

primary open surgery (laparotomy)

chances > 70% of conversion from laparoscopy to laparotomy (estimated by the surgeon prior to surgery)

emergency surgery

refusal of the patient or care takers

contra-indication for intravenous lidocaine

contra-indication for thoracic epidural (cohort 1)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2019
Enrollment:	44
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46162
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7468
NTR-old	NTR7710
CCMO	NL67209.099.18
OMON	NL-OMON46162

Study results