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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON46162

Source
ToetsingOnline

Brief title
SELECT

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colorectal tumors, malignant en benigne

Research involving

Human

Sponsors and support

Primary sponsor: Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: abdominal wall katheters, colorectal surgery, ERAS, thoracic epidural

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

Colorectal cancer is still the world*s leading cause of death. To offer patients a smooth planning and performance of their surgery is one mayor goal, that the Wilhelmina Hospital achieves. 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.
Optimal recovery after colorectal surgery is also the main goal of all ERAS (early recovery after surgery) guidelines.

The actual ERAS statement regarding intra- and postoperative analgesia recommends to not use thoracic epidural catheters in laparoscopic surgery anymore as a gold standard. After years of glorification of this technique it seems to be classified as over-treatment nowadays and needs to be replaced by other techniques fitting the minimized surgical trauma.
Unfortunately the ERAS society does not give clear advice to date how to replace a good working epidural catheter within a multimodal anesthetic regimen.

Study objective

There is evidence however that abdominal wall blocks, such as TAP blocks, could help managing the postoperative pain, but covering the visceral pain is not possible with this technique. It is not even clear to date which component of pain, the abdominal wall pain or the viscero-sensoric pain, play the mayor role postoperatively. It just seems logically, that only treating one part may not be sufficient and may lead to a higher opioid consumption.
To not take any advantage of the modern peripheral nerve or compartment block techniques would mean to step back to general anesthesia alone.
Since there is enough evidence that opioid based general anesthesia, followed by an opioid containing postoperative analgesic scheme is not state of the art in cancer treatment, 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 - intraabdominal as-well as preperitoneal.
The catheters cannot be placed preoperatively hence the possibility of preemptive analgesia is simply not existing. To make sure that the comparison with an already preoperative working epidural catheter makes sense, the patients in the investigational group will receive an infusion of Lidocaine started with induction of general anesthesia.
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.

Study design

The study will be designed as a prospective cohort study. We will include 22 patients per cohort.
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 and intravenous Lidocaine 1% during the surgical procedure. At the end of surgery the surgeon will place two OnQ silver soaker multi hole catheters.
Both groups will receive a standardized general anesthesia and postoperative analgesics.

Intervention

see study design

Study burden and risks

Patients in cohort 1 do ondergoed the standard rises of an thoracic epidural catheter. This is a wel known, decennia old technique and resembles the golden standard, Hence this technique is not under investigation here and so the possible risks are no part of this study.
Patients in cohort 2 undergo the risk of an transcutaneous katheter placement like bleeding, local infection and katheter displacement.
In comparison to the much more invasive epidural the risks are seen as mild to moderate. The benefits like better mobility and shorter length of stay which make an adjuvant therapy possible much sooner, outweigh those risks by far.

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

ASA 1-3
benign or malign indication for laparoscopic right/ left sided hemicolectomy of 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
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:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-07-2018
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO

Date:	18-04-2019
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20161
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL67209.099.18

Register	ID
OMON	NL-OMON20161