Spinal Bupivacaine/Morphine in laparoscopic gastro-intestinal surgery

Published: 31-07-2013
Last updated: 15-05-2024

The objective of this study is to determine if a single spinal shot of morphine can decrease post-operative opioid-use, and thereby decrease opioid side-effects and lead to a quicker recovery after surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON41666

Source
ToetsingOnline

Brief title
Spinal bupivacaine/morphine in laparoscopic surgery

Condition

- Gastrointestinal therapeutic procedures

Synonym
Post-operative pain, wound pain

Research involving
Human

Sponsors and support

Primary sponsor: Maasstad Ziekenhuis
Source(s) of monetary or material Support: Maasstad Ziekenhuis

Intervention

Keyword: laparoscopic GI-surgery, Post-operative pain, Spinal morphine

Outcome measures

Primary outcome

elective laparoscopic gastro-intestinal surgery in adults

Secondary outcome

Opioid-use in the post-operative phase, side-effects of opioids, mobilisation,

, patient-satisfactory, difficulty of surgery, compliance of the abdominal wall

during surgery and NK-cell activity

Study description

Background summary

There is a lot of interest in increasing the speed of recovery after a surgery. Many programs have been initiated to this purpose, one of its' most known is ERAS (Enhanced Recovery After Surgery). In this program, advices are given in order to pursue a quick recovery. An important aspect within ERAS is post-operative analgesia. When pain is well treated, there is a decreased risk of pneumonia, less stress-respons resulting in a favourable cardial oxygen-balance and less ileus, all resulting in a quicker recovery.
For open abdominal surgery (laparotomy), the thoracic epidural analgesia is the golden standard. However, for laparoscopic surgery, the thoracic epidural results in prolonged hospital stay, probably because the pain in laparoscopic surgery is not as hard as in laparotomic surgery. Ergo, the risks of the thoracic epidural does not seem to outweigh the benefits in laparoscopic surgery.
An alternative is the Patient Controlled Analgesia-pump (PCA-pump), in which the patient supplies itself with intravenous opioid, based on a preset manner. Although the analgetics effect are very well, it has side-effects as sedation, itch, nausea and ileus. These side effects are dependent on the amount of opioids administered.
Recently, there is an increasing attention for administering intrathecal opioids by a single shot spinal. Potential benefits as oppose to the thoracic epidural is a the single shot technique instead of catheter resulting in less infection-risk, the possibility for a quicker mobilisation, and still results

in very high levels of analgesia. In regard to the PCA-pump is that there will be less need of systemic opioids, and thus resulting in less side-effects. Furthermore, there are suggestions that spinal anesthesia results in a higher oxygen delivery to the bowels, and probably gives a better healing with less complications.
The method of a single shot opioid is well known, it has been used by caesarian sections and orthopedic surgery. In laparoscopic surgery, as an addition to general anesthesia, it has only been investigated in 3 studies. Although these studies show very promising results, by methodological issues these results cannot be transfered to the Dutch situation.
Kong et al. have compared spinal bupivacaine vs. bupivacaine/morphine in laparoscopic gastro-intestinal surgery. They noticed higher levels of analgesia in the first 48 hours after surgery. However, they did not report if it resulted in a shorter hospital stay or quicker mobilisation and the study was not performed in an ERAS-setting.
Virlos et al. compared the thoracic epidural vs. the single shot spinal bupivacaine/diamorphine in an observational study, based on a change of practise. They reported better analgesia, a quicker mobilisation and a earlier hospital discharge in the spinal-group.
Wongyingsinn et al. have compared the single shot spinal with bupivacaine/morphine vs. the PCA-pomp and noticed a better analgesia in the first 24 hours, but no earlier discharge or mobilisation. However, this study was probably underpowered to detect an effect on length of hospital stay, and the additional (on demand) analgetics in the single shot spinal group were different than the general Dutch practise.

There is an issue of which opioid to use. Many different opioids can and are used intrathecally in daily practise. For a prolonged effect, a hydrophilic opioid is required, because of the slower diffusion. In the Netherlands, morphine is the most used hydrophilic opioid, that is registered for spinal administration. It has been well investigated, although its' dose remains an issue for debate.

Hypothesis:
We expect that in laparoscopic gastro-intestinal surgery, a single shot spinal with bupivacaine/morfine will result in a beter analgesia in the first 48 hours. Hereby, the patients will require less systemic opioids, which will decrease the side-effects. Furthermore, we expect the patients to recover quicker and show an earlier mobilisation and a shorther hospital stay.

Study objective

The objective of this study is to determine if a single spinal shot of morphine can decrease post-operative opioid-use, and thereby decrease opioid side-effects and lead to a quicker recovery after surgery.

Study design

Single-blinded Randomized Controlled Trial

Intervention

A single spinal shot of bupivacaine/morphine

Study burden and risks

A single shot spinal injection, performed sterile and with local anesthesia.
The patients will be asked to fill in a diary during the hospital-stay.
Bloodsamples will be drawn on day 0, 1 and 3.

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

Laparoscopic Gastro-intestinal surgery

Exclusion criteria

Bariatric surgery, rectal surgery, kidney-failure, Aorta-valve stenosis, coagulation disorders, emergency surgery

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2014
Enrollment:	56
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Marcaine
Generic name:	Bupivacaine
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Morphine
Generic name:	Morphine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	31-07-2013
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	01-07-2015
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	29-06-2017
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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: 24841
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-001167-22-NL
CCMO	NL43488.101.13
OMON	NL-OMON24841

Study results

Date completed: 18-10-2016

Actual enrolment: 60