Combined intracutaneous and intraperitoneal anaesthesia for postoperative pain reduction after laparoscopic cholecystectomy

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To analyse the effect of preoperative intracutaneous and intraperitoneal instillation of levobupivacaine on postoperative pain after laparoscopic cholecystectomy

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON33385

Source
ToetsingOnline

Brief title
Intense trial

Condition

- Gastrointestinal conditions NEC

Synonym
gallstones, symptomatic gallstone disease

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cholecystectomy, intraperitoneal, laparoscopic, levobupivacaine

Outcome measures

Primary outcome

Postoperative Visual Analogue Score is conducted just before the procedure and afterwards at 30 min, 2h, 4h, 8h, and 24 hours, split in shoulder pain and abdominal pain. The abdominal/shoulder pain scores will also be split in rest, cough and movement pain

Secondary outcome

- Rescue analgesia treatment. Rescue analgesia will be given when the pain score (VAS) rises above 40.
- Adverse events caused by the investigational procedure or by levobupivacaine itself.
- Length of the surgical procedure
- Length of hospital stay
- Time to resumption of work or other usual daily activities
- Development of postoperative complications during hospitalisation including pneumonia, thrombosis, urinary tract infections, wound abscess and bile leakage.
- Development of intraoperative complications including perforation of the gallbladder, bile duct injury, bowel injury and injury to vascular structures.
- The presence of persistent postoperative pain after three months

Study description

Background summary

Laparoscopic surgery is associated with fewer complications, reduced post-operative pain, reduced length of hospitalisation and less use of analgesia. However, abdominal pain and shoulder pain are still very common side effects associated with laparoscopy. To further reduce postoperative pain, long acting local anaesthetics are a promising solution. These local anaesthetics can be used for trocar- and port-site wound infiltration to prevent abdominal pain and for intraperitoneal instillation and visceral infiltration to reduce deep abdominal pain and referred shoulder pain.
Two long acting local anaesthetics are favourable for a long lasting nerve block; levobupivacaine (chirocaine®) and ropivacaine (naropin®), mainly because of their low toxic profile. However, there is lack of evidence whether levobupivacaine, administrated preoperatively intracutaneous and intraperitoneally, gives significant pain reduction.
Therefore we constructed a randomised study to investigate if preoperative local and intraperitoneal instillation of levobupivacaine reduces postoperative pain and thus length of hospitalisation and use of analgesics in patients who undergo elective laparoscopic cholecystectomies for symptomatic gallstone disease compared to a normal saline control group.

Study objective

To analyse the effect of preoperative intracutaneous and intraperitoneal instillation of levobupivacaine on postoperative pain after laparoscopic cholecystectomy

Study design

Prospective, randomised double blinded clinical trial. Experiment group n = 40 and a placebo group n = 40. Total n = 80.

Intervention

A total of 20 mL (1,25 mg/mL levobupivacaine or normal saline) is administered subcutaneously at all trocar sites before surgery. In addition, 60 mL (1,25 mg/mL LB or saline) is administered in the intraperitoneal cavity at the site of the gallbladder and right hemidiaphragm after creation of the pneumoperitoneum and placement of trocars

Study burden and risks

The burden for the patient is being questioned six times. The most severe risk

is a convulsion caused by accidentally administrating the local anaesthetic intravascular, thereby inducing an overdose. Another rare risk may include an allergic reaction to the amid-type local anaesthetic.
The potential value of this study is a significant post operative pain reduction after laparoscopic cholecystectomy, which may be translated to other laparoscopic procedures. The advantage of pain reduction is a lower perceived burden for the patient, shorter hospitalization and a faster recovery.
Moreover, the postoperative use of analgesics may be reduced.

Contacts

Public
Meander Medisch Centrum

Utrechtseweg 160
3818 ES Amersfoort
NL
Scientific
Meander Medisch Centrum

Utrechtseweg 160
3818 ES Amersfoort
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The patients who will be included are 18-75 of age and ASA I&II, which means that no or mild systemic disease is present according to the classification system of the American Society of

Anaesthesiologists. The patients are included when a surgeon sets the indication for a laparoscopic cholecystectomy. The indication is symptomatic gallstone disease. If the laparoscopic cholecystectomy transfers to an open procedure, the patients will receive an equal follow up (intention-to-treat principle).

Exclusion criteria

- Patients with cholecystitis, septic shock from cholangitis, severe acute pancreatitis, advanced cirrhosis, and gallbladder cancer
- Patients with a medical history of epilepsy, cardiac arrhytmias or chronical pain of any kind .
- If a patient is allergic to drugs of the amid type.
- Pregnancy
- Subject suffering from hypotension or hypovolemia.
- Subjects suffering from liver disease
- Subject using drugs which deduce function of the CYP3A4 system like ketoconazol.
-Subject using drugs which deduce function of the CYP1A2 system like the methylxanthines(Fluvoxamin enoxacin)
- Patients with conditions making them incapable of filling out the questionnaires.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-08-2009
Enrollment:	80
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Chirocaine
Generic name:	Levobupivacaine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	08-06-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-06-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EudraCT	EUCTR2009-012639-13-NL
CCMO	NL28180.100.09