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

Published: 08-06-2009 Last updated: 04-05-2024

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

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## 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**

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## **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

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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