

The effect of low pressure pneumoperitoneum and pulmonary recruitment maneuver on postoperative pain after laparoscopic cholecystectomy

Submission date 25/09/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/11/2017	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 03/11/2017	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Operations for gallstone disease are still sometimes painful. It can cause pain both in the upper abdomen (upper stomach) but also in the shoulder. Research has shown that the intra-abdominal pressure and the residual (left over) CO₂ gas (used to provide space in the abdomen to do the operation by minimal invasive surgery) can lead to more pain after surgery. The aim of the study is to look if the pain can be reduced by manually removing the residual CO₂ gas by a pulmonary recruitment manoeuvre. This manoeuvre puts pressure in the lungs to then deflate the abdomen by evacuating the CO₂ out of the abdomen via the surgical incisions.

Who can participate?

Adults aged 18 and older who are undergoing elective surgery for gall stone removals.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive their surgical procedure done to the standard level of care. Those in the second group receive the pulmonary recruitment manoeuvre at the end of surgery. Participants are followed up after the surgery during their hospital stay for pain levels, nausea and vomiting. Participants receive a telephone call 48 hours after surgery to assess the quality of their recovery.

What are the possible benefits and risks of participating?

There are no benefits or risks for the patients.

Where is the study run from?

AZ Groeninge (Belgium)

When is the study starting and how long is it expected to run for?

December 2014 to March 2017

Who is funding the study?
Dienst Anesthesie AZ Groeninge (Belgium)

Who is the main contact?
Dr Isabelle Casier

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2014-005442-22

Protocol serial number
AZGS2014160

Study information

Scientific Title
The effect of low pressure pneumoperitoneum and pulmonary recruitment maneuver on postoperative pain after laparoscopic cholecystectomy

Study objectives
Hypothesis:
The addition of a recruitment manoeuvre to a low pressure pneumoperitoneum will lead to an additional reduction in postoperative pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board AZ Groeninge Kortrijk, 31/03/2015, ref: 1510

Primary study design
Interventional

Study design

Prospective randomized controlled single blind trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Optimalisation of pain relief after laparoscopic cholecystectomy

Interventions

Low pressure pneumoperitoneum in all patients

Pulmonary recruitment maneuver at the end of the surgery in 1 of the 2 groups

Participants are randomly allocated to one of two groups:

Group 1: Control group

Group 2: Intervention group

Randomisation is done beforehand using the website: 'www.randomization.com'. Randomisation is blind to the participations as they will not know which group they have been allocated to. The anesthesiologist and surgeon do know which group because a recruitment manoeuvre can't be blinded.

All the patients require a laparoscopic cholecystectomy for gall stone disease. The laparoscopy is performed with a low pressure pneumoperitoneum (8-10mmHg). Those in the second group receive a pulmonary recruitment maneuver at the end of surgery. Those in the first group receive the standard level of care.

The recruitment manoeuvre is done by an anesthesiologist. Patient was placed in 30° Trendelenburg position, the trocars were fully open to allow CO2 removal. The anesthesiologist gives two manual pulmonary inflation to a maximum pressure of 40cmH2O. Each one of the inflations takes five seconds.

The follow-up was done in the recovery room and at the nursing department during the length of hospitalisation (+/-36 hours). The following parameters are recorded for each group: VAS (visual analogue scale) pain score, need of pain killer, nausea and vomiting.

48 hours after surgery, a quality of recovery is measured by a questionnaire answered by telephone.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Pain relief during the first 24 hours is measured using the VAS (visual analogue scale) at fixed time point: 0-1-6-12-18-24 hours postoperatively.

Key secondary outcome(s)

1. Total analgesic use during the first 24 hours is measured: the amount of using/need of painkilling during hospitalisation (difference in need of morphine sulphate and tramadol IV (in milligram))
2. Recovery after 48 hours is measured using the postoperative 15-item patient-rated quality of recovery questionnaire by telephone call

3. Nausea and vomiting is measured using patient personal experience
4. Length of hospital stay is measured using time in hours
5. Requirement for increased pressure during surgery is measured using: the place in the abdomen that is required to operated

Completion date

01/03/2017

Eligibility

Key inclusion criteria

1. Patients for elective laparoscopic surgery for gall stone disease
2. ASA I and II
3. More than 18 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Refusal to give consent
2. Cholecystitis
3. BMI above 35
4. Intolerance to one of the pain medication
5. Pregnancy

Date of first enrolment

26/05/2015

Date of final enrolment

20/06/2016

Locations

Countries of recruitment

Belgium

Study participating centre
AZ Groeninge
President Kennedylaan 4
Kortrijk
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8500

Sponsor information

Organisation
AZ Groeninge Dienst Anesthesie

ROR
<https://ror.org/01cz3wf89>

Funder(s)

Funder type
Government

Funder Name
Dienst Anesthesie AZ Groeninge

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from isabelle.casier@azgroeninge.be

IPD sharing plan summary

Available on request