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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

Registration date
08/11/2017

Overall study status
Completed

Last Edited
03/11/2017

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 manoeuver. This manoeuver 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

EudraCT/CTIS number
2014-005442-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective randomized controlled single blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files in Dutch and French

Health condition(s) or problem(s) studied
Optimalisation of pain relief after laparoscopic cholecystectomy

Interventions
Low pressure pneumoperitoneum in all patiënts
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 manoeuver 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 manoeuver 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 measure
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.

Secondary outcome measures
1. Total analgesic use during the first 24 hours is measured: the amount of using/needing 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

Overall study start date
01/12/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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
Belgium
8500

Sponsor information

Organisation
AZ Groeninge Dienst Anesthesie

Sponsor details
AZ Groeninge
Pres Kennedylaan 4
Kortrijk
Belgium
8500

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01cz3wf89

Funder(s)

Funder type

Government

Funder Name
Dienst Anesthesie AZ Groeninge

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/05/2018

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