Postlaparoscopic reduction of pain by combining intraperitoneal normal saline and the pulmonary recruitment maneuver

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A promising strategy to reduce postlaparoscopic shoulder pain and abdominal pain is the pulmonary recruitment maneuver. By using manual pulmonary inflations, the intraperitoneal pressure increases and removal of residual carbon dioxide will be...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON42258

Source
ToetsingOnline

Brief title
POLAR BEAR trial

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
Postlaparoscopic shoulderpain.

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Intraperitoneal normal saline, Laparoscopy, Pulmonary recruitment maneuver, Shoulderpain

Outcome measures

Primary outcome

The primary outcomes are the incidence and intensity of postlaparoscopic pain

in shoulder and upper abdomen at 8, 24 and 48 hours after surgery, using the

Visual Analog Score scale (VAS scale).

Secondary outcome

The secondary outcomes are postoperative use of pain medication, nausea and

vomiting, and pulmonary problems.

Study description

Background summary

Shoulder pain and pain in the upper abdomen are common complaints after laparoscopy. The incidence of shoulder pain ranges from 35 to 80%. Sometimes this laparoscopy-related pain is even worse than the pain at the incision site. Laparoscopy*induced pain is thought to be caused by retention of carbon dioxide in the abdomen, which irritates the phrenic nerve and diaphragm and causes referred pain in the shoulder and pain in the upper abdomen.

Study objective

A promising strategy to reduce postlaparoscopic shoulder pain and abdominal pain is the pulmonary recruitment maneuver. By using manual pulmonary inflations, the intraperitoneal pressure increases and removal of residual carbon dioxide will be facilitated. Another method is the use of intraperitoneal normal saline infusion. As carbon dioxide is lighter than normal saline, it rises and escapes the abdomen more easily. Besides, normal saline is thought to offer as a physiologic buffer system to dissolve excess carbon dioxide. In this randomized study, reduction of postlaparoscopic pain

will be estimated by using a combination of the two therapies mentioned.

Study design

Randomized controlled trial, in two teaching hospitals in the Netherlands.

Intervention

In the intervention group, the upper abdomen will be evenly and bilaterally filled with warmed isotonic normal saline (15-20 ml/kg body weight) and left in the abdominal cavity. Then the patient is placed in Trendelenburg position (30 degrees), and the anesthesiologist will perform five manual pulmonary insufflations with a pressure of maximum 40 cm H2O (pulmonary recruitment maneuver). The fifth positive pressure inflation will be held for 5 seconds.
The trocar sleeve valves will be left open, so the carbon dioxide can escape the abdominal cavity. Then de patient is placed in neutral position and the instruments are removed from the abdomen.
In the control group, the carbon dioxide is removed from the abdominal cavity at the end of the surgery, with gentle abdominal pressure and passive exsufflation through the port sites, with the sleeve valves open.

Study burden and risks

Previous studies show that intraperitoneal normal saline infusion is a safe procedure. Likewise, the pulmonary recruitment maneuver is a proven safe procedure when inflating with a maximum pressure of 40 cm H2O. Literature shows there are no related complications with these two interventions. Participants fill out short questionnaires at three different moments, 8, 24 and 48 hours after surgery. 24 Hours postoperative, patients are phoned to ask for (serious) adverse events. The expected benefit is a decrease in incidence and severity of pain in shoulder and upper abdomen after laparoscopic surgery.

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

Women between 18-65 years of age, ASA classification I-II, who are planned for an elective laparoscopic procedure with a benign gynecologic indication.

Exclusion criteria

-Women who do not speak Dutch
-Women younger than 18 years
-Women who had a midline laparotomy before
-Pregnant women
-COPD/Emphysema
-Daily use of pain medication
-Allergic/intolerance to NSAID*s

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2015
Enrollment:	126
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-03-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-07-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL50655.015.14

Study results

Date completed:	15-10-2015
Actual enrolment:	127