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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27538

Source
Nationaal Trial Register

Brief title
POLAR BEAR trial

Health condition

laparoscopy; laparoscopie
shoulder pain; schouderpijn
intraperitoneal saline; fysiologisch zout intraperitoneaal
pulmonary recruitment maneuver

Sponsors and support

Primary sponsor: Dr. M.Y. Bongers, gynecologist
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Source(s) of monetary or material Support: -

Intervention

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 complications.

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. 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. Normal saline offers 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 objective

In this randomized study, reduction of incidence and intensity of postlaparoscopic pain will be estimated by using a combination of two therapies, intraperitoneal normal saline and the pulmonary recruitment maneuver.

Study design

Patients will receive questionnaires to record pain scores, other complaints, and use of pain medication at 8, 24 and 48 hours postoperative.

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 the 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.

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Eligibility criteria

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 laparotomy before

-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)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2014
Enrollment:	126
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4643
NTR-old	NTR4812
Other	: POLAR-1

Study results