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

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27538

Bron
Nationaal Trial Register

Verkorte titel
POLAR BEAR trial

Aandoening

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

Ondersteuning

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Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2014
Aantal proefpersonen:	126
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4643
NTR-old	NTR4812
Ander register	: POLAR-1

Resultaten