

Pressure

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20713

Source

NTR

Brief title

PRESSURE

Health condition

Benign gynaecological conditions (vaginal blood loss, endometrial abnormalities, cysts, myomas, endometriosis etc) which can be operated laparoscopically

Benigne gynaecologische aandoeningen (vaginaal bloedverlies, afwijkingen aan endometrium, myomen, cystes, endometriose enz) welke laparoscopisch geopereerd kunnen worden

Sponsors and support

Primary sponsor: afdeling gynaecologie in het Zuyderland

Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

TOF-scores (compared to peroperative events >> when the patient reacts) and Postoperative painlevels (shoulder, abdominal, other)

Secondary outcome

nausea and vomiting

length of hospital stay

operation duration

Study description

Background summary

This study is a baseline measurement at gynaecologic laparoscopic surgeries. We want to know if gynaecologists and anaesthesiologists work according to specific protocols about intraperitoneal pressure levels, the level of neuromuscular blockade and pain medication.

During surgery a TOF-watch is attached to the patient. The investigator fills out a self-developed data collection form: Items on this form are: Duration of surgery, medication (sleep- and pain medication, muscle relaxants), positioning of the patient, the intraperitoneal pressures, events that occur during surgery, Actions of the anaesthesiology nurse, TOF values.

After surgery patients receive a questionnaire where they have to fill out their postoperative pain levels: shoulder pain, abdominal pain and incisional pain. Further they have to fill out if they took pain medication, if they had any nausea or vomiting and if they took medication to prevent that. Measurement moments are: 1 hour and 3 hours post-operatively, 3 times a day at day 1-3 and 1 time a day at day 4-7.

Study objective

With help of the TOF watch, a reduction in muscle relaxation can be observed earlier. In this way, perioperative events (pain or contractions by the patient) can be prevented. Less perioperative events lead to less postoperative pain.

Study design

- Degree of muscle relaxation measured during surgery using the TOF watch.
- Postoperative pain measured during one week after surgery: 1 hour and 3 hours post-operatively, 3 times a day at day 1-3 and 1 time a day at day 4-7.

Intervention

TOF WATCH: this device will be placed at the hand of the patient. TOF scores are blinded from the surgeon and anesthetist. The rest of the surgery will be just as normal.

Contacts

Public

Henri Dunantstraat 5
Nadine Weijermans
Gynaecology and Obstetry

Heerlen 6419 PC
The Netherlands

Scientific

Henri Dunantstraat 5
Nadine Weijermans
Gynaecology and Obstetry

Heerlen 6419 PC
The Netherlands

Eligibility criteria

Inclusion criteria

- Female, 18yr and older
- benign gynaecological laparoscopies and early staged malignancies
 - o Hysterectomy, o Cystectomy o Adnexectomy o Tubectomy o Adhesiolysis
 - o Endometriosis removal o Myomectomy o sterilisation
 - o
 - Essure verwijdering
 - o
 - Figo 1-2 (t/m stadium 2)
 - endometrium carcinoom
 -

Kan informed consent lezen en ondertekenen

Exclusion criteria

malignant diseases with metastasis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	22-05-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion	
Date:	17-05-2017
Application type:	First submission

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	NL6242
NTR-old	NTR6422
Other	METC Zuyderland Heerlen : 17-N-74

Study results