

Pressure

Gepubliceerd: 17-05-2017 Laatste bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20713

Bron

NTR

Verkorte titel

PRESSURE

Aandoening

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

Ondersteuning

Primaire sponsor: afdeling gynaecologie in het Zuyderland

Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

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 dat occur durig surgery, Actions of the anaesthesiology nurse, TOF values.

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

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Henri Dunantstraat 5
Nadine Weijermans
Gynaecology and Obstetry

Heerlen 6419 PC
The Netherlands

Wetenschappelijk

Henri Dunantstraat 5
Nadine Weijermans
Gynaecology and Obstetry

Heerlen 6419 PC
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Female, 18yr and older
- benign gynaecological laparoscopies and early staged malignancies
 - o Hysterectomy, o Cystectomy o Adnexextirpation 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

malignant diseases with metastasis

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	22-05-2017
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	17-05-2017
Soort:	Eerste indiening

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

Resultaten