Laparoscopic advanced Imaging Techniques in Endometriosis therapy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25841

Source
Nationaal Trial Register

Brief title
LITE

Health condition

endometriosis

Sponsors and support

Primary sponsor: VU medical center
Source(s) of monetary or material Support: Department of surgery

Intervention

Outcome measures

Primary outcome

- Sensitivity

Secondary outcome

- Specificity

- Negative and positive predictive value

- Descriptive analysis of the by endometriosis affected ovaries and intestines.

- Descriptive analysis of the difference in detection between superficial (peritoneal) endometriosis and deep endometriosis.

- Descriptive and quantitative analysis of the occurrence of (serious) adverse events.

-Time of the procedure / operation time in minutes.

Blood loss in millilitres.

Direct costs; ICG, medical equipment,

Study description

Background summary

RATIONALE: Despite it’s proven efficacy, recurrence rates after endometriosis surgery remain a major challenge and a crucial issue in the long-term management of endometriosis. Insufficient treatment due to the polymorphic appearance of endometriosis lesions is common. Remaining untreated lesions are the supposed origins of recurrences and subsequent unsuccessful treatment. So called non-pigmented ‘red’ lesions are hard to distinguish from normal peritoneal tissue. Previous studies have shown that image enhancement modalities such as narrow-band imaging (NBI), near-infrared fluorescent imaging with indocyanin green (ICG) and three-dimensional laparoscopy (3D) may improve endometriosis detection and therefore may also effect treatment outcomes.
OBJECTIVE: The aim of this pilot trial is to examine which advanced image enhanced modality is the most feasible for the detection of endometriosis lesions, with respect to the sensitivity and specificity of the investigated modalities. This in order to set up a larger scale randomised clinical trial.
STUDY POPULATION: Female patients who are planned to undergo laparoscopic treatment of endometriosis.
INTERVENTION: During laparoscopy selected regions will be inspected and photographed with 3D-imaging, NBI and ICG in a systematically randomized different order. Biopsies of suspected endometriosis lesions are taken. Control biopsies of healthy peritoneum will be taken to compare the healthy and affected tissue. Patients will receive ICG through an infuse during surgery.

Study objective

The use of advanced imaging techniques will result in increased sensitivity of detecting peritoneal endometriosis

Study design

Only intra-operative intervention, no follow-up

Intervention

Intra-operative identification of peritoneal with the following imaging techniques:

- Narrow-band Imaging (NBI)

- Three-dimensional imaging (3D)

- Near-infrared imaging with Indocyanin Green (ICG)
Biopsies of endometriosis lesions and healthy peritoneum will be taken.

Contacts

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Eligibility criteria

Inclusion criteria

- Oral and written informed consent

- Age 18 years and older

- Premenopausal stage

- Elective laparoscopic treatment of endometriosis lesions by CO 2 laser/ bipolar diathermy or surgical excision.

- Presence of endometriosis (ASRM III-IV) confirmed by previous laparoscopy or likely to be present based on TVUS or MRI, including uni- or bilateral ovarian endometrioma.

- Regular preoperative work-up

Exclusion criteria

- Legally or mentally incapable or unable to give informed consent

- ASA (American Society of Anaesthesiologists) score higher than 3

- Major open abdominal surgery in the past

- Pregnancy

- Malignancy

- Iodine allergy

- Hypersensitivity reaction to prior usage of indocyanin green injection

- Use of any of the following medication: any anticonvulsive medicine, bisulphites, haloperidol, heroin, meperidine, metamizol, methadone, morfine, nitrofurantoine, opiate alkaloids, fenobarbital, fenylbutazon, cyclopropane, probenicid and rifamycin.

- Chronic kidney failure (eGFR<55)

- Chronic liver failure (ASAT, ALAT, AF and yGT > two times the max normal value)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43974
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5470
NTR-old	NTR5614
CCMO	NL52456.029.15
OMON	NL-OMON43974

Study results