Laparoscopic advanced Imaging Techniques in Endometriosis therapy

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25841

Bron
NTR

Verkorte titel
LITE

Aandoening

endometriosis

Ondersteuning

Primaire sponsor: VU medical center
Overige ondersteuning: Department of surgery

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Sensitivity

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Only intra-operative intervention, no follow-up

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

VU Medical Centre
Boelelaan 1118

Marit Lier
Amsterdam 1081 HZ
The Netherlands
020 4445278

Wetenschappelijk

VU Medical Centre
Boelelaan 1118

Marit Lier
Amsterdam 1081 HZ
The Netherlands
020 4445278

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2016

Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43974
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten