The Use of Indocyanine Green-Based Fluorescence Imaging for Intraoperative Detection of Peritoneal Endometriosis

Published: 14-12-2016
Last updated: 19-04-2024

Objective: Using near-infrared fluorescence (NIRF) with a Karl Storz® NIR fluorescence laparoscope to provide a real-time intra-operative enhanced visualization of endometriosis during diagnostic laparoscopy. Thus improving identification of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON47083

Source
ToetsingOnline

Brief title
Fluorescence Imaging for Intraoperative Detection of Endometriosis

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
endometriosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endometriosis, fluorescense imaging, Indocyanine green

Outcome measures

Primary outcome

Main study parameters/endpoints: Investigate the feasibility of identification of endometriotic lesions with (conventional non-robotic) fluorescence laparoscopy equipment with preoperative or peroperative ICG administration. Assessment will be performed using an intraoperative registration form (see attachment), postoperative video-analysis (with determination of the target-to-background ratio) and with histological confirmation. Biopsies will be taken from suspicious endometriotic areas seen with both the conventional white light mode and NIRF-mode, areas that appear only with white light mode or NIRF-mode and areas without any visible or fluorescent areas. Histologic examination is carried out on the biopsies to confirm the diagnosis.

Secondary outcome

-

Study description

Background summary

Rationale:
Endometriosis, defined as the presence of endometrial tissue outside the uterine cavity, is a common disease affecting 10-15% of women of reproductive age and up to 90% of women with pelvic pain. The gold standard for diagnosis of endometriosis is the combination of laparoscopy with histological confirmation. However, during laparoscopy using conventional white light imaging, endometriotic lesions can appear red and vascular, white and scarred, black, brown, yellow, or almost any colour, thus making it difficult to identify .

Our hypothesis is that the use of indocyanine green-based (ICG) fluorescence imaging during laparoscopy will provide a real-time intraoperative image enhancement for detection of endometriotic lesions by using the hypervascular characteristic of this disease.

Study objective

Objective: Using near-infrared fluorescence (NIRF) with a Karl Storz® NIR fluorescence laparoscope to provide a real-time intra-operative enhanced visualization of endometriosis during diagnostic laparoscopy. Thus improving identification of endometriosis for complete resection of the affected areas and increasing efficiency of the procedure.

Study design

Study design: A prospective observational pilot study.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will receive intraoperative injections of ICG in addition to the standard care. Moreover, biopsies will be taken to be sent for histological confirmation of endometriosis and normal tissue. The biopsies taken from sites that are visible with conventional white light are a part of the standard procedure. However, additional biopsies may be taken at sites that appear only after injection of the dye. Furthermore, a biopsy will be taken from the sites not showing any suspicious lesions in both modes as a negative control sample. These will be the additional (minimally) invasive actions for the patient. The last 5 patients to be included, will receive the administration of ICG prior to surgery, simultaneously with the induction of anesthesia.
Initially, patients participating in this study will not benefit from the application of NIRF during the surgical procedure. The laparoscopic fluorescence imaging system itself is not related to any kind of additional risk for the patient.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

boschstraat 105E
Maastricht 6211AW
NL

Scientific
Medisch Universitair Ziekenhuis Maastricht

boschstraat 105E
Maastricht 6211AW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:
Patients scheduled for elective laparoscopic surgery in which endometriosis is suspected or proven
Able to understand the nature of the study and what will be required of them
Females
Age >18years
Premenopausal
No history of impaired liver and renal function
No history of hypersensitivity or allergy to indocyanine green
Willing to participate

Exclusion criteria

Not able to give written informed consent
Males
Aged < 18 years
Pregnant or breast-feeding women
Known indocyanine green hypersensitivity or allergy
Not willing to participate

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2017
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Near infrared fluorescence laparoscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	11-04-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL54458.068.15