Intra-operative near-infrared fluorescence imaging of the bowel during endometriosis surgery with indocyanine green: a pilot study

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The primary objective is to assess the feasibility of intravenous injection of ICG to detect the border between healthy - and therefore fluorescent - bowel versus endometriosis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON49910

Source
ToetsingOnline

Brief title
Intra-operative imaging endometriosis with ICG

Condition

- Menstrual cycle and uterine bleeding disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
endometriosis, endometrium outside the uterus

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endometriosis, Fluorescence guided surgery, Indocyanine Green

Outcome measures

Primary outcome

The difference in the borders between bowel endometriotic nodule and healthy bowel. These borders will be determined by using indocyanine green to visualize the healthy bowel, compared to determination with conventional white light.

Secondary outcome

1. Assessment of the pathological, clinical and patient characteristics and correspondence to the non-fluorescent character of the endometriotic nodule.

2. The fluorescent difference between bowel and endometriotic nodule at 2 moments during surgery, measured intra-operatively by the surgeon and post-operatively by the researcher via operative images.

3. Assessment of potential added value of intra-operative visualization of endometriosis through a questionnaire for the surgeon

Study description

Background summary

The distinction between endometriotic tissue and healthy tissue is difficult. Removal of bowel endometriosis can be done via shaving, discoid resection or segmental resection. While shaving results in the least complications, segmental resection results in the lowest recurrence rates. One could potentially use shaving for more patients, with more complete resection, if endometriosis visibility is optimized. Fluorescence with indocyanine green could be used for this purpose in bowel endometriosis, as the bowel is highly vascularized and therefore fluorescent, compared to the fibrotic endometriotic

nodule.

Study objective

The primary objective is to assess the feasibility of intravenous injection of ICG to detect the border between healthy - and therefore fluorescent - bowel versus endometriosis.

Study design

Pilot study in one centre, with 15 patients.

Intervention

All patients will receive a repeated dose of 5 mg ICG at two moments: after visualization of the endometriotic bowel nodule and right before segmental resection.

Study burden and risks

The burden for patients is low. No extra visits are necessary for this study. Moreover no extra blood samples, physical examinations, questionnaires or other tests will take place.
The non-investigational product (ICG) is safely used for over 60 years for multiple indications (including the one in this study, tissue perfusion). Only mild allergic reactions have been seen. Patients with known a known allergic reaction to ICG or a substance related to ICG are excluded. Conventional care is not altered by the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Scheduled for laparoscopic removal of bowel endometriosis, by segment resection;
2. Patients aged over 18 years old;
3. Has the ability to communicate well with the Investigator in the Dutch language and willing to comply with the study restrictions;
4. Signed informed consent prior to any study-mandated procedure;

Exclusion criteria

1. Known allergy or history of adverse reaction to ICG, iodine or iodine dyes;
2. Severe liver insufficiency;
3. Hyperthyroidism or a benign thyroid tumour;
4. Pregnant or breastfeeding women;
5. Any condition that the investigator considers to be potentially jeopardizing the patients well-being or the study objectives (following a detailed medical history and physical examination;
6. Subject taking phenobarbital, phenylbutazone, primidone, phenytoin, haloperidol, nitrofurantoin, probenecid;
7. Emergency surgery

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2022
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	29-10-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25350
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL78266.058.21
OMON	NL-OMON25350

Study results

Date completed:	19-01-2023
Actual enrolment:	15