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

No registrations found.

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

Summary

ID

NL-OMON25350

Source
Nationaal Trial Register

Brief title
Intra-operative imaging endometriosis with ICG

Health condition

Patients with bowel endometriosis

Sponsors and support

Primary sponsor: Haaglanden Medical Center
Source(s) of monetary or material Support: HMC

Intervention

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 laparoscopic white light.

Secondary outcome

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

Study description

Background summary

Rationale: 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.
Objective: The primary objective is to assess the feasibility to detect the border between healthy – and therefore fluorescent- bowel and endometriosis by using intravenous indocyanine green. This is measured by the difference in border between the assessment with ICG compared to conventional laparoscopic white light assessment.

Study objective

By administering ICG, the bowel will be fluorescent, as it is highly vascularized. As the endometriotic nodule contains fibrosis, the nodule will be less fluorescent compared to the bowel. Using this difference, the border between endometriosis and healthy bowel can be determined more precisely compared to conventional surgery.

Study design

Tissue perfusion will be assessed directly after injection of ICG.

Intervention

All patients will receive a repeated dose of 5 mg ICG at two moments

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2021
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-11-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49910
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9837
CCMO	NL78266.058.21
OMON	NL-OMON49910

Study results