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

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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...

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

## Samenvatting

### ID

NL-OMON25350

**Bron**
NTR

**Verkorte titel**
Intra-operative imaging endometriosis with ICG

**Aandoening**

Patients with bowel endometriosis

### Ondersteuning

**Primaire sponsor:** Haaglanden Medical Center
**Overige ondersteuning:** HMC

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

Tissue perfusion will be assessed directly after injection of ICG.

### Onderzoeksproduct en/of interventie

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

# Contactpersonen

### Publiek

Leids Universitair Medisch Centrum
Fokkedien Tummers

+3171 5262796

### Wetenschappelijk

Leids Universitair Medisch Centrum
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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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;

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

# 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: | 01-12-2021 |
| Aantal proefpersonen: | 15 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 01-11-2021 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49910
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten