

# Intra-operative fluorescent imaging of the tumor border and sentinel lymph nodes in rectal and sigmoid cancer

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27686

### Source

NTR

### Brief title

GREEN LIGHT

### Health condition

Bowel cancer

## Sponsors and support

**Primary sponsor:** Leiden University Medical Center (LUMC)

**Source(s) of monetary or material Support:** Leiden University Medical Center (LUMC)

## Intervention

## Outcome measures

### Primary outcome

1. Percentage of patients in whom SLN identification was possible using NIR fluorescence imaging

2. Percentage of patients in whom intraoperative detection of the tumor border was possible by NIR fluorescence imaging

### **Secondary outcome**

Time difference between visualization of fluorescence signal and Indian ink tattoo. Sensitivity of SLN procedure.

## **Study description**

### **Background summary**

The SLN procedure has been proposed to improve nodal staging in colorectal cancer patients. Moreover, the resection margins is prognostic in survival after rectal cancer surgery. Current treatment includes neoadjuvant chemoradiation therapy, which often result in regression of the tumor. This makes intraoperative tumor detection more difficult. Intraoperative endoscopic marking of the tumor can assist in detection of tumor border and possibly decrease tumor involvement of the resection margin. Moreover, intraoperative endoscopic marking of the tumor can result in detection of the SLNs.

### **Study objective**

Intraoperative endoscopic marking of the tumor can assist in detection of tumor border and possibly decrease tumor involvement of the resection margin. Moreover, intraoperative endoscopic marking of the tumor can result in detection of the SLNs.

### **Study design**

The primary and secondary outcomes will be assessed during surgery and pathological assessment.

### **Intervention**

After general anesthesia, prior to incision, ICG;NanoColl will be injected endoscopically around the tumor. During surgery, fluorescence imaging will be performed to visualize tumor border and lymph nodes.

## **Contacts**

### **Public**

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## **Eligibility criteria**

### **Inclusion criteria**

Colorectal cancer patients scheduled for laparoscopic low anterior resection.

### **Exclusion criteria**

1. History of allergy to iodine, shellfish, indocyanine green or nanocolloid;
2. Pregnancy;
3. Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.

## **Study design**

### **Design**

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	28-10-2013
Enrollment:	20
Type:	Anticipated

## Ethics review

Not applicable	
Application type:	Not applicable

## 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
NTR-new	NL4541
NTR-old	NTR4682
Other	: P09.001 METC LUMC

## Study results

## Summary results

NA