# Intra-operatieve fluorescente beeldvorming van schildwachtklieren bij maagkankerpatienten

No registrations found.

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

# **Summary**

### ID

NL-OMON28011

**Source** Nationaal Trial Register

Brief title GREEN LIGHT

**Health condition** 

Gastric 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**

Identification rate, defined as the proportion of patients in whom sentinel and non-sentinel lymph nodes was identified with the fluorescent signal of ICG:Nanocoll.

#### Secondary outcome

Tumor-to-background ration, accuracy, sensitivity, specificity.

# **Study description**

#### **Background summary**

SLN technique has been used in the management of a variety of cancers to avoid unnecessary lymphadenectomy, and also in gastric cancer several studies support the validity of the SLN concept.

Fluorescent imaging using near-infrared probes is an innovative technique to directly visualize lymphatic pathways and lymph nodes.

Previous studies already used indocyanine green (ICG) in SLN mapping in gastric cancer and were able to successfully identify SLN with either preoperative submucosal and intraoperative subserosal injections around the tumor. Less false negative cases were found after preoperative submucosal injection. However, also a more widely spread of ICG in the lymphatic vessels with time, which results in the detection of more 2nd-tier nodes. Recent publications showed good retention in the SLN with ICG coupled to a nanocolloid. The aim of the study is to determine the proportion of gastric cancer patients in whom SLNs can be identified non-invasively with fluorescent imaging using ICG coupled to a nanocolloid (ICG:Nanocoll) during standard lymphadenectomy.

#### **Study objective**

Fluorescent near-infrared imaging can accurately detect lymph nodes non-invasively during SLN mapping in gastric cancer patients.

#### Study design

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

#### Intervention

Standard lymphadectomy will be performed. During surgery, the near-infrared dye ICG:Nanocoll will be injected around the tumor and lymphatic pathways and lymph nodes will be visualized non-invasively using our experimental camerasystem.

# Contacts

#### Public

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# **Eligibility criteria**

### **Inclusion criteria**

gastric cancer patients scheduled for (partial)

gastric resection and lymphadenectomy.

### **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):	01-02-2013
Enrollment:	20
Туре:	Anticipated

# **Ethics review**

Positive opinion	
Date:	27-11-2013
Application type:	First submission

# **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	NL4129

4 - Intra-operatieve fluorescente beeldvorming van schildwachtklieren bij maagkanker ... 21-06-2025

Register	ID
NTR-old	NTR4280
Other	METC LUMC : P09.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# **Study results**

Summary results

N/A