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# Intraoperative detection of ovarian cancer metastases using near-infrared fluorescence imaging and indocyanine green

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 19/08/2014 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 11/09/2014 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 26/06/2015 | Cancer | |

## Plain English summary of protocol

Background and study aims
Ovarian cancer is one of the most common cancers among women. Unfortunately, because early symptoms can be vague and somewhat similar to other conditions, it is often not diagnosed until it has reached an advanced stage and spread (metastasized) to other areas of the body. Surgery is useful in two ways; to remove tumors and to discover how far the cancer has spread (known as tumor staging). It is sometimes difficult to see all the tumors until surgery has begun and finding them all even during surgery can be a challenge, particularly when trying to find smaller ones. However, a new method, near-infrared fluorescent (NIRF) imaging has been developed that can see ovarian tumor tissue during surgery. In early studies it has been shown that ovarian cancer can be identified using NIRF imaging and a special dye called near-infrared fluorescent dye indocyanine green. This is because the dye tends to accumulate in tumors much more readily than they do in normal tissues (called the enhanced permeability and retention - or EPR - effect). We want to see how many tumors are seen using the new technique.

Who can participate?
Adult women aged at least 18 years either diagnosed with, or suspected to have, ovarian cancer and due for tumor staging or cytoreductive surgery (surgery to remove the tumor(s)) .

What does the study involve?
Ovarian cancer patients have indocyanine green given to them intravenously during surgery and NIRF performed to make the tumors easier to see. The number of tumors are then counted and a health professional (pathologist) then looks at the tumors that are removed to see how advanced the disease has become.

What are the possible benefits and risks of participating?
Possible benefits include finding more tumors that would otherwise be the case during surgery. A possible risk is an allergic reaction to indocyanine green. However, this is very rare (< 1 out of 20.000) and can be managed by the anaesthesiologist.

Where is the study run from?
Leiden University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
October 2012 to October 2015

Who is funding the study?
Leiden University Medical Center (Netherlands)

Who is the main contact?
Dr Alexander Vahrmeijer
a.l.vahrmeijer@lumc.nl
Dr. Katja Gaarenstroom
k.n.gaarenstroom@lumc.nl

# Contact information

### Type(s)
Scientific

### Contact name
Dr Alexander Vahrmeijer

### Contact details
Albinusdreef 2
Leiden
Netherlands
2333 ZA

# Additional identifiers

### Protocol serial number
P10.001

# Study information

### Scientific Title
Intraoperative detection of ovarian cancer metastases using near-infrared fluorescence imaging and indocyanine green: a open-label, exploratory, non-randomised clinical trial

### Acronym
GREENLIGHT

### Study objectives
Near-infrared fluorescence imaging using indocyanine green can assist in the intraoperative detection of ovarian cancer metastases

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics Committee of the Leiden University Medical Center, 27/07/2012, ref: P10.001/NV/nv

### Study design
Open-label exploratory non-randomised clinical trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Ovarian cancer

### Interventions
Intravenous administration of 20 mg Indocyanine Green

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
The number of intraoperative detected metastases using near-infrared fluorescence imaging and indocyanine green.This will be measured during surgery. When new anatomical sites are exposed during surgery, color images and NIR fluorescent images are obtained. After surgery, the Pathologist will perform histological assessment of the resected lesions for tumor status.

### Key secondary outcome(s))
1. Sensitivity and specificity of detected fluorescent hotspots
2. Concordance between fluorescence signal and pathology assessment

Sensitivity and specificity of the fluorescent signal will be calculated after tumor status of theresected lesions is assessed. Concordance will also be calculated after surgery with theobtained information on fluorescence signal and tumor status of the resected lesions.

### Completion date
01/10/2015

## Eligibility

### Key inclusion criteria
1. All patients diagnosed with or suspected for ovarian cancer planned for staging or cytoreductive surgery
2. Age >18 years old

### Participant type(s)
Patient

**Healthy volunteers allowed**
No

**Age group**
Adult

**Lower age limit**
18 years

**Sex**
Female

**Key exclusion criteria**
1. Renal impairment (defined as eGFR<55)
2. History of allergy to iodine, shellfish or indocyanine green
3. Patient pregnant or lactating

**Date of first enrolment**
01/10/2012

**Date of final enrolment**
01/10/2015

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Albinusdreef 2**
Leiden
Netherlands
2333 ZA

# Sponsor information

**Organisation**
Leiden University Medical Center (Netherlands)

**ROR**
https://ror.org/05xvt9f17

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Leiden University Medical Center (Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 25/06/2015 | | Yes | No |