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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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/10/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
15

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)

Sponsor details
Albinusdreef 2
Leiden
Netherlands
2333 ZA

Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Center (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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