Detection of residual tumor tissue during surgery in ovarian cancer.

No registrations found.

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

Summary

ID

NL-OMON24387

Source
NTR

Brief title
N/A

Health condition

ovarian cancer
eierstokkanker
ovariumkanker

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: UMCG

Intervention

Outcome measures

Primary outcome

Intra-operative detection of ovarian cancer by a folate-FITC enhanced optical imaging device, in which visual inspection in combination with routine histology is considered the golden standard for the presence of tumour tissue.

Secondary outcome

Presence of fluorescent residual disease after intended radical resection by visual observation alone.

Study description

Background summary

This project consists of the realization followed by the clinical validation of a procedure dedicated to residual disease localization in the case of ovarian cancer. An intra-operative near-infrared fluorescence (NIRF) imaging camera and the use of a NIRF optical contrast agent will be evaluated for its feasibility to detect residual disease in patients with ovarian cancer. In order to improve the prognosis of ovarian cancer, residual disease is one of the few factors that can be influenced by more optimal cytoreductive surgery. The end-goal of this intra-operative imaging procedure is to significantly improve the detection and efficiency of the technique in order to reduce the amount of residual tumour tissue. Gynecologic oncologists, surgeons and fundamental physics applied to medical imaging researchers are involved in this project.

Study objective

Improved detection of tumor.

Study design

Debulking surgery.

Intervention

Administration of folate-FITC prior to surgery. During surgery, a near-infrared fluorescence intra-operative camera system will be used to detect residual tumor tissue.

Contacts

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Eligibility criteria

Inclusion criteria

1. Female > 21 years old;

2. Ovarian cancer for which debulking surgery is scheduled.

Exclusion criteria

1. Renal, cardiac or pulmonary failure (ASA III-IV);

2. Present or previous hyperthyreoidism;

3. Iodine allergy or previous anaphylactic reactions;

4. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-08-2009
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	NL1867
NTR-old	NTR1980
Other	UMCG/CCMO : BICG07UMCG-NIRF/NL26980.042.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A