Detection of residual disease using Folate-FITC enhanced optical imaging in ovarian carcinoma

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To test a near-infrared fluorescence camerasystem in order to detect folate-FITC in tumour tissue in women with ovarian cancer who undergo cytoreductive surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON33039

Source
ToetsingOnline

Brief title
Residual disease detection with folate-FITC

Condition

- Reproductive neoplasms male malignant and unspecified
- Obstetric and gynaecological therapeutic procedures

Synonym
ovarian carcinoma, residual disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Folate-FITC, Intra-operative, Ovarian Cancer, Residual Disease

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 (proven bij biopsy)

Study description

Background summary

Ovarian cancer is a disease that is usually detected in a late stage, when the disease has already spread and/or has formed metastases. This leads to a bad prognosis. Treatment consists of cytoreductive surgery, in which as much tumour tissue as possible is removed. The extent of cytoreduction; i.e. the amount of tumour tissue that is removed and the size of residual disease afterwards; has great influence on the prognosis. By removing more tumour tissue during cytoreductive surgery, the prognosis can be improved.
Tactile and visual observation ("naked eye") are currently the only ways in which the surgeon / gynecologic oncologist can assess the presence of tumour tissue. In this study, we will test a near-infrared fluorescence (NIRF) camera system in order to detect tumour tissue intra-operatively. The fluorescent signal is created by injecting a fluorescent tracer prior to surgery. Subesequently, the operative procedure is carried out as usual. The only difference in this are the moments in which an optical image is acquired by the intra-operative camera. WIth the aid of these images, the surgeon / gynecologic oncologist could detect more tumour tissue. This will possibly result - in the future - in a more complete cytoreduction with less residual disease. This influences prognosis in a positive manner.

Study objective

To test a near-infrared fluorescence camerasystem in order to detect folate-FITC in tumour tissue in women with ovarian cancer who undergo cytoreductive surgery.

Study design

Interventional phase 0 technical feasibility study: non-randomized, open label, uncontrolled with single group assignment.

Study burden and risks

Before the surgical procedure, patients undergo one extra test that is normally not a part of the pre-operative diagnostic testing:
- Pregnancy test; in case of a postive pregnancy test, patient will be excluded from the study.

Four hours prior to surgery, patients will receive an intravenous injection with folate-FITC. The biggest risk of this is an allergic or anaphylactic reaction.

The use of the intera-operative camera does not cause any risk in itself, but by using the camera, the total operative time can be extended with ~15 minutes.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

female > 21 yrs of age; operable ovarian carcinoma

Exclusion criteria

Pregnant women, significant renal, cardiac, or pulmonary disease (ASA III-IV), History of iodine allergy or anaphylactic reactions to insect bites or medication, presence or history of hyperthyroidism

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2009
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	folate-FITC
Generic name:	folate-fluorescein isothiocyanate

Ethics review

Approved WMO Date:	18-05-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2009-010559-29-NL
CCMO	NL26980.042.09