Evaluation of near-infrared fluorescence (NIRF) imaging for sentinel lymph node (SLN) detection in squamous cell carcinoma of the vulva: a feasibility study

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To test an intra-operative fluorescent camera system with a fluorescent optical agent in detection of the sentinel lymph node. This will be compared to the standard method with radiocolloid and patent blue.

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON33082

Source
ToetsingOnline

Brief title
Sentinel node detection in vulvar cancer

Condition

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

Synonym
sentinel lymph node, vulvar carcinoma

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: Imaging, Indocyanin Green, Sentinel Node, Squamous cell carcinoma of the vulva

Outcome measures

Primary outcome

the number and localisation of sentinel lymph node(s) detected with the camera

and ICG, compared to the detection with radiocolloid and patent blue

Secondary outcome

n/a

Study description

Background summary

Vulvar cancer is a disease that occurs in 2 per 100.000 women per year in the Netherlands. Treatment exists of surgical removal of the tumour combined with the sentinel node procedure with radiocolloid and patent blue. Affected lymph nodes are excised. This requires an injection one day prio to surgery.
With the aid of an intra-operative fluorescent camera system and a fluorescent optical agent, the sentinel node could possibly be detected intra-operatively. If this is a safe and sensitive method, the injection one day prior to surgery could be abandoned.

Study objective

To test an intra-operative fluorescent camera system with a fluorescent optical agent in detection of the sentinel lymph node. This will be compared to the standard method with radiocolloid and patent blue.

Study design

Phase 0 interventional / technical feasibility study, non-randomized,

uncontrolled, open label

Intervention

Injection of ICG together with patent blue (golden standard)

Study burden and risks

The burden on the patient consist of an injection with ICG during surgery, under full anaesthesia. The risk of this injection is an allergic reaction. Because the procedure takes place in the OR, such a reaction can be treated directly and adequately. Also, there can be a green discolouration of the skin on the site of injection. This will disappear within 2 weeks.

Contacts

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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 with biopsy proven squamous cell carcinoma of the vulva who are eligible for a sentinel node procedure

Exclusion criteria

Pregnant women, significant renal (creatinine > 110 ug/l), 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: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	ICG Pulsion
Generic name:	Indocyanin Green
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	12-06-2009
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	EUCTR2009-010561-23-NL
CCMO	NL26982.042.09