Sentinel lymph node procedure in patients with recurrent vulvar squamous cell carcinoma. A multicentre observational study.

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The primary objective is to investigate the safety of replacing complete IFL by the SLN procedure in patients with local recurrent vulvar squamous cell carcinoma without suspicious groin lymph nodes.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON54845

Source
ToetsingOnline

Brief title
Sentinel Node Procedure in Recurrent Vulvar Carcinoma.

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Vulvovaginal disorders (excl infections and inflammations)
- Obstetric and gynaecological therapeutic procedures

Synonym
vulvacarcinoma, Vulvar cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Inguinal lymph node dissection, Local recurrent Vulva Carcinoma, Sentinel node procedure

Outcome measures

Primary outcome

Primary end point is the number of groin recurrences after SLN procedure.

Secondary outcome

Success rate of the SLN procedure, surgical drawbacks, wound healing problems,

long term sequela, and quality of life in women treated for a 1st recurrent

vulvar cancer.

Study description

Background summary

Standard groin treatment in recurrent vulvar cancer consists of an uni or bilateral inguinal lymph node dissection (IFL), whereas in the primary setting a sentinel lymph node (SLN) procedure is performed in case of unifocal tumours < 4cm without suspicious groin lymph nodes at imaging. The advantages of SLN procedure over an IFL are obvious: the short and long term sequels such as wound healing problems, lymph cyst formation, recurrent erysipelas and lymph oedema are much less common after SLN procedure. In a national retrospective analysis we showed that SLN is feasible in selected recurrent vulvar cancer patients. This national prospective observational study aims to investigate the safety of such procedure. Since little is known on the outcome of 1st recurrent vulvar cancer we also gather more information on women with a first recurrence, not eligible for the SLN procedure.

Study objective

The primary objective is to investigate the safety of replacing complete IFL by

the SLN procedure in patients with local recurrent vulvar squamous cell carcinoma without suspicious groin lymph nodes.

Study design

This is predominantly a prospective multicentre observational study on sentinel lymph node (SLN) procedure in women with local recurrent vulvar cancer. Besides it is an observational study on the treatment and outcome of women with a local recurrent vulvar cancer, not eligible for the SLN procedure.

Study burden and risks

In this study, similar to the current routine, preoperative imaging of chest, abdomen and groins is performed. The patient is informed about the standard procedure and about the option of a SLN procedure. She and her treating gynaecologist decide on the preferred treatment. Prior to surgery the planned surgical procedure is recorded, including patients* consent for IFL in case the SLN procedure fails. The surgical procedure (SLN procedure) will be less extensive compared to routine IFL, with less unfavourable short and long term effects, such as infections and lymph oedema. In case of groin metastases detected in the SLN procedure further treatment is warranted, either by surgery (uni or bilateral IFL) and/or by radiotherapy. At follow up participants will undergo (non-invasive) ultrasonography studies of the groin at 6 and 12 months. Participants will be asked to fill in additional questionnaires at baseline, 6 and 12 months. In case of a groin recurrence (due to failed SLN procedure) further treatment is warranted, probably resulting in a poorer prognosis with a high mortality rate (probably 80-90%). Currently, robust data on the occurrence of groin recurrence after either SLN biopsy or IFL for recurrent vulvar cancer is lacking. Given the lower morbidity and less short and long term side effects of the SLN procedure compared to IFL an additional 5% failure rate is considered acceptable.

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

In order to be eligible for the study (non SLN cohort and SLN cohort, group A-C): - Possible to understand and read Dutch. - Possible to understand the study and give informed consent. - No age limit specified. - Patients should mentally, physically and geographically be able to undergo follow-up. In order to be eligible to undergo the SLN procedure, a subject must meet all of the following criteria: - First local recurrent SCC of the vulva. - Previous treatment with wide local excision or (partial) vulvectomy tumours < 4 cm., not encroaching in urethra, vagina or anus with clinically negative inguinofemoral lymph nodes. - Localisation and size of the tumour are such that perilesional injection of the tracers at three or four sites is possible. - Preoperative imaging does not show enlarged (> 10 mm sort axis) or suspicious nodes. - Fit for surgery

Exclusion criteria

Potential subject who meets any of the following criteria should not undergo the SLN procedure in the study arm (A-B), the patient can be asked for the non SLN cohort. - Inoperable tumours and tumours with diameter > 4 cm. - Patients with inguinofemoral lymph nodes at palpation clinically suspect for metastases, at radiology enlarged (> 10 mm short axis) / suspicious groin nodes and with cytological proven inguinofemoral lymph node metastases. - A history of bilateral IFL and radiotherapy to the groins. - A lateral tumour and history of ipsilateral IFL and ipsilateral radiotherapy. - Tumour encroaching urethra, vagina, or anus. - Previous surgery of the vulva was not radical (margin < 1

mm) and additional treatment (2nd surgery or radiotherapy) was not performed. - Multifocal recurrent disease of the vulva. - Synchronous, non- curable 2nd malignancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2020
Enrollment:	243
Type:	Actual

Ethics review

Approved WMO Date:	12-05-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	05-09-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL70149.078.19