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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22671

Source
Nationaal Trial Register

Brief title
V2SLN

Health condition

vulva cancer

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

To investigate the safety of replacing complete IFL by SLN procedure in women with a first

recurrent vulvar SCC in tumours < 4 cm.

Secondary outcome

1) To investigate the feasibility of the SLN procedure in patients with a first recurrence of vulvar SCC. (Success rate of the SLN procedure, surgical drawbacks)
2) To evaluate the short and long-term morbidity associated with the sentinel lymph node procedure in patients with a first recurrence of vulvar SCC.(complications, wound healing problems, long term sequela, quality of life)
3) To evaluate the short and long-term morbidity associated with treatment of a first recurrence of vulvar SCC.(complications, wound healing problems, long term sequela, quality of life)

Study description

Background summary

Rationale: Standard groin treatment in recurrent vulvar cancer consists of a 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.

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 population: Women with their first local recurrence of vulvar cancer, 18 years and older, fit for surgical treatment, who had previous groin treatment as part of the primary treatment: none, uni- or bilateral SLN procedure, or IFL and/or radiotherapy. Excluded are women with previous ipsilateral IFL and radiotherapy, or bilateral IFL and radiotherapy. Women that do not fulfil these criteria will be included in the observational arm.

Intervention: Surgical treatment consists of standard local treatment (wide local resection, vulvectomy) of the vulvar tumour combined with a uni- or bilateral SLN procedure.

Main study parameters/endpoints: Primary end point is the number of groin recurrences after SLN procedure. Secondary endpoints: 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

The sentinel node procedure is feasible and safe in women with a first recurrent vulva cancer

Study design

A first and second insight in feasibility will be given after the inclusion of 40 resp 100 patients

Intervention

Sentinel node procedure

Contacts

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Eligibility criteria

Inclusion criteria

- 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

A 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 controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
De-identified participant data on patient level and related documents (e.g., study protocol) are available for sharing. Requests can be addressed to H.C. van Doorn at h.vandoorn@erasmusmc.nl. In general, requests made by physicians and epidemiologists for research, teaching, and clinical purposes will be granted in a timely matter and shared in a secured way obeying our hospital policies.

Ethics review

Not applicable

Application type:	Not applicable

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	NL8467
Other	METC ErasmusMC : MEC-2020-0021

Study results