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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22671

Bron
Nationaal Trial Register

Verkorte titel
V2SLN

Aandoening

vulva cancer

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate the safety of replacing complete IFL by SLN procedure in women with a first recurrent vulvar SCC in tumours < 4 cm.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Sentinel node procedure

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2020
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8467
Ander register	METC ErasmusMC : MEC-2020-0021

Resultaten