GROningen INternational Study on Sentinel nodes in Vulvar cancer. An observational study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23376

Source
NTR

Brief title
GROINSS-V II

Health condition

Squamous cell carcinoma of the vulva

Sponsors and support

Primary sponsor: Dutch Cancer Society (KWF Kankerbestrijding)
Source(s) of monetary or material Support: KWF Kankerstichting

Intervention

Outcome measures

Primary outcome

Groin recurrence rate

Secondary outcome

Treatment associated morbidity.

Study description

Background summary

The Groningen International Study on Sentinel nodes in Vulvar cancer (GROINSS-V) II investigated whether inguinofemoral radiotherapy is a safe alternative to inguinofemoral lymphadenectomy (IFL) in vulvar cancer patients with a metastatic sentinel node (SN). It was a prospective multicentre phase 2 treatment trial, including patients with early-stage squamous cell carcinoma (SCC) of the vulva (diameter <4cm) without signs of lymph node involvement at imaging, who had primary surgical treatment with SN-biopsy. Where the SN was positive for disease (metastasis of any size), radiotherapy was given to the inguinofemoral region (50Gy). Stopping rules were defined for the occurrence of groin recurrences.

Study objective

Is is safe to replace inguinofemoral lymphadenectomy by adjuvant radiotherapy in early stage vulvar cancer patients with a metastatic SN?

Study design

7 October 2016 accrual completed, October 2018 follow-up completed

Intervention

Radiotherapy instead of inguinofemoral lymphadenectomy in patients with SN metastasis

Contacts

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Eligibility criteria

Inclusion criteria

1. Primary squamous cell carcinoma of the vulva < 4cm
2. Depth of invasion > 1mm;
3. Not encroaching in urethra, vagina or anus, and clinically negative inguinofemoral lymph nodes;
4. Preoperative imaging does not show enlarged (< 1.5 cm) / suspicious nodes;
5. Possibility to obtain informed consent.

Exclusion criteria

1. Inoperable tumors and tumors with diameter > 4cm;
2. Patients with inguinofemoral lymph nodes, at palpation clinically suspect for metastases, at radiology enlarged (>1.5 cm) / suspicious groin nodes and with cytologically proven inguinofemoral lymph node metastases;
3. Patients with multifocal tumors.

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:	Recruitment stopped
Start date (anticipated):	01-12-2005

Enrollment:	1500
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-01-2006
Application type:	First submission

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	NL552
NTR-old	NTR608
Other	METC Groningen : METc2005/099
ISRCTN	ISRCTN37773303

Study results

Summary results

N/A