GROINSS-V III - Radiochemotherapie bij een uitzaaiing in de schildwachtklier

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22105

Source
NTR

Brief title
GROINSS-V III

Health condition

Vulvar cancer
Sentinel node procedure
Lymph node metastasis
Vulvacarcinoom
Schildwachtklierprocedure
Lymfogene metastasen

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Dutch Cancer Society (KWF Kankerbestrijding)

Intervention

Outcome measures

Primary outcome

Groin recurrence rate in the first two years after primary treatment.

Secondary outcome

- Treatment related morbidity (CTC AE v 4.0)

- Disease-specific survival

- Patient-reported quality of life

Study description

Background summary

Standard treatment of early stage vulvar cancer is a wide local excision of the primary tumor combined with the sentinel node (SN) procedure for the groins. An inguinofemoral lymphadenectomy (IFL) is only indicated in patients with a positive SN. An IFL is associated with major morbidity, e.g. wound healing problems, lymphoceles, lymphedema of the legs and recurrent infections. GROINSS-V II investigated whether radiotherapy would be a safe alternative for IFL in patients with metastasis in their SN. The results for radiotherapy in the group with metastasis ≤ 2mm are promising. This study also showed that for patients with metastasis > 2mm, only radiotherapy was not efficient. The efficacy of treatment can be increased by adding chemotherapy or giving a higher dose of radiotherapy. In GROINSS-V III we will investigate this regimen.

Study objective

In vulvar cancer patients with a macrometastasis in the sentinel lymph nodes, chemoradiation is as effective as an inguinofemoral lymphadenectomy, but is associated with less treatment-related morbidity.

Study design

After primary treatment, patients will be followed-up 3-monthly for two years. Groin recurrence rate will be monitored continuously with stopping rules for the occurence of groin recurrences.

QOL will be evaluated at 6, 12, 18 and 24 months after primary treatment.

Intervention

Patients will be treated with chemoradiation, in a total dose of 56Gy to the involved site, combined with weekly cisplatin 40mg/m2

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Histological confirmed primary SCC of the vulva

- T1 tumor, not encroaching urethra/vagina/anus

- Depth of invasion > 1mm

- Tumor diameter < 4cm

- Unifocal tumor

- No enlarged (>1.5cm) or suspicious inguinofemoral lymph nodes at imaging (CT/MRI/ultrasound)

- Possibility to obtain informed consent

- Metastatic sentinel lymph node; size of metastasis > 2mm and / or extracapsular extension, or

- Metastatic sentinel lymph node: more than 1 SN with metastasis ≤ 2mm

- Patients are able to understand requirements of study, provide written informed consent and comply with the study and follow-up procedures

- Adequate bone marrow, renal and liver function:

• Absolute neutrophil count ≥ 1.5 x 109 /L

• Platelet count ≥ 100 x 109 /L

• Creatinine clearance ≥ 40 ml/min measured by the Cockroft Gault formula

• Total bilirubin < 1.25 x ULN

• Aspartate transaminase (AST) and alanine transaminase (ALT) ≤ 2.5 x ULN

- Performance status of 0, 1 or 2 on the Eastern Cooperative Oncology Group (ECOG) Scale (Appendix A)

- Age 18 years or older

- Life expectancy of ≥ 12 weeks

- Written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Inoperable tumors and tumors > 4cm

- Multifocal tumors

- Tumors with other pathology than squamous cell carcinoma

- Patients with enlarged / suspicious lymph nodes which are proven metastatic after fine needle aspiration cytology

- No other carcinomas, other than basal cell carcinomas, within last 5 years

- History of pelvic radiotherapy

- History of any infection requiring hospitalization or antibiotics within 2 weeks before enrollment

- Pregnant female or nursing mother

- Desire to become pregnant

- Known brain or spinal cord metastases unless adequately treated (surgery or radiotherapy) with no evidence of progression and neurologically stable off anticonvulsants and steroids

- Unstable angina, myocardial infarction, cerebrovascular accident, > Class II congestive heart failure according to the New York Heart Association Classification for Congestive Heart Failure (see Appendix B) within 6 months before enrollment

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	157
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

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	NL7435
NTR-old	NTR7677
Other	METc Groningen : 2016-00601; 2016-003973-16 Eudract nummer

Study results

Summary results

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