# De status van het micromilieu van de (schildwacht)klieren en tumor bij patiënten met HPV-positieve en HPVnegatieve kanker van de schaamlippen.

No registrations found.

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

# Summary

### ID

**NL-OMON25060** 

Source NTR

**Brief title** GINA (vulva)

#### **Health condition**

Vulvar cancer Lymph nodes HPV Vulvacarcinoom Lymfeklieren HPV

## **Sponsors and support**

Primary sponsor: NKI-AVL Source(s) of monetary or material Support: KWF

### Intervention

### **Outcome measures**

#### **Primary outcome**

To analyse the microenvironment of (S)LNs and PT (i.e. various T-cell populations, antigen presenting cells and myeloid suppressor cells) and other immune factors produced by the tumour cells in patients with vulvar cancer.

#### Secondary outcome

- to assess the differences of the microenvironment in HPV-positive and HPV-negative (S)LNs

- to assess the difference of the microenvironment of tumour-negative and metastatic (S)LNs.

- to assess the difference of the microenvironment of SLNs and non-SLNs.

Exploratory objectives:

- to analyse the difference in the (S)LNs compared to the PT.

# **Study description**

#### **Background summary**

This is an exploratory study to further delineate the microenvironment of the primary tumour and (sentinel) lymph nodes (SLN) in HPV-positive and HPV-negative vulvar cancer. All patients diagnosed with vulvar carcinoma who will undergo a sentinel node procedure or a lymphadenectomy/lymph node debulking will be asked to participate in the study. Patients who will undergo a lymphadenectomy will be asked to participate in detecting the SLNs prior to the lymph node dissection by injecting patent blue in the tumour margins before the (local) excision of the tumour (if applicable) on the operation room. In case only a lymph node dissection/debulking and no local excision of the tumour will be performed, the patient will be asked permission to obtaina small tumour biopsy on the operation room.

#### **Study objective**

This is an exploratory study to further delineate the microenvironment of the PT and (S)LNs in HPV-positive and HPV-negative vulvar cancer.

#### Study design

All interventions will be performed on the same day

#### Intervention

Patients who will undergo a lymphadenectomy will be asked to participate in detecting the SLNs prior to the lymph node dissection by injecting patent blue in the tumour margins before the (local) excision of the tumour (if applicable) on the operation room. In case only a lymph node dissection/debulking and no local excision of the tumour will be performed, the patient will be asked permission to perform a small tumour biopsy on the operation room.

Different subsets of the antigen presenting cells and other immune cells in the microenvironment will be measured by the use of multi-color flow cytometry and multi-parameter immunohistochemistry.

# Contacts

Public

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# **Eligibility criteria**

## **Inclusion criteria**

- Age  $\geq$  18 years at start of the study;

 Primary carcinoma of the vulva with an indication for sentinel node procedure or inguinofemoral lymphadenectomy;

- Operation at the NKI-AVL or AMC/VUmc;
- Signed informed consent.

# **Exclusion criteria**

- Patiënts who had previous therapy for macro invasive vulvar cancer (including sentinel node procedure) will not participate in the sentinel node part of the study.

# Study design

## Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-02-2018
Enrollment:	100
Type:	Unknown

# **Ethics review**

Positive opinion	
Date:	21-12-2017
Application type:	First submission

# **Study registrations**

## Followed up by the following (possibly more current) registration

ID: 44257 Bron: ToetsingOnline Titel:

# Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL6843
NTR-old	NTR7021
ССМО	NL61965.031.17
OMON	NL-OMON44257

# **Study results**