

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

Gepubliceerd: 21-12-2017 Laatste bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25060

Bron

Nationaal Trial Register

Verkorte titel

GINA (vulva)

Aandoening

Vulvar cancer
Lymph nodes
HPV
Vulvacarcinoom
Lymfeklieren
HPV

Ondersteuning

Primaire sponsor: NKI-AVL

Overige ondersteuning: KWF

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To analyse the microenvironment of (S)LN's 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 obtain a small tumour biopsy on the operation room.

Doel van het onderzoek

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

Onderzoekopzet

All interventions will be performed on the same day

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	100
Type:	Onbekend

Ethische beoordeling

Positief advies	
Datum:	21-12-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44257

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten