De status van het micromilieu van de (schildwacht)klier en tumor bij patiënten met baarmoederhalskanker.

No registrations found.

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

Summary

ID

NL-OMON22029

Source
NTR

Brief title
GINA (cervix)

Health condition

Cervical cancer
Lymph nodes
HPV
Cervixcarcinoom
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. antigen presenting cells and other immune cells) and other immune

factors produced by the tumour cells in patients with cervical cancer.

Secondary outcome

- to assess the difference of the microenvironment of tumour-negative and metastatic LNs

- to assess the difference of the microenvironment of SLNs and nonSLNs

- to analyse the difference in the (S)LNs compared to the primary tumour

- to assess the effect of the cervical tumour on the systemic immunity

Study description

Background summary

This is an exploratory study to further delineate the microenvironment of the primary tumour and (sentinel) lymph nodes in cervical cancer.All patients diagnosed with cervical carcinoma who will undergo an operation or a lymphadenectomy 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 ICG/patent blue in the tumour before the operation starts in the operation room. Patients who will undergo a lymph node debulking in the context of chemoradiotherapy, will be asked permission to obtain a small tumour biopsy.

Study objective

This is an exploratory study to further delineate the microenvironment of the PT and (S)LNs in cervical cancer.

Study design

- blood will be drawn before surgery and 3 months after surgery

Intervention

- patients will be asked to give permission to search for sentinel node(s), by injecting patent blue

- patients will be asked to donate 2x 10 ml blood for further analysis (at two different timepoints)

Contacts

Public
VUmc-Cancer Center Amsterdam, CCA 2 - 48

Jossie Rotman
Obstetrics & Gynecology/Immunotherapy Lab

Amsterdam
The Netherlands
(020-44)42175 Mob: +31622706702
Scientific
VUmc-Cancer Center Amsterdam, CCA 2 - 48

Jossie Rotman
Obstetrics & Gynecology/Immunotherapy Lab

Amsterdam
The Netherlands
(020-44)42175 Mob: +31622706702

Eligibility criteria

Inclusion criteria

- Age ≥ 18 years at start of the study;

- Primary carcinoma of the cervix;

- Operation at the NKI-AVL or AMC/VUmc;

- Signed informed consent.

Exclusion criteria

- Patients with cervical cancer other than squamous, adeno- or adenosquamous origin.

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:	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

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6842
NTR-old	NTR7020
Other	NL62567.031.17 : M17GINC

Study results