The state of the (sentinel) lymph node and tumour microenvironment in patients with cancer of the cervix.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON44376

Source
ToetsingOnline

Brief title
Microenvironment lymph nodes and tumour cervical cancer

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cervical cancer, cervix carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF-subsidie

Intervention

Keyword: Cervical cancer, HPV, Lymph nodes

Outcome measures

Primary outcome

To analyse the microenvironment of (sentinel) lymph node(s) and primary tumour (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 lymph nodes

- to assess the difference of the microenvironment of sentinel lymph nodes and non-sentinel lymph nodes

- to analyse the difference in the (sentinel) lymph nodes compared to the primary tumour

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

Study description

Background summary

Cervical cancer is the fourth most common cancer worldwide. When treatment consists of an operation, pelvic lymph nodes are removed to detect the presence of metastases. Sentinel lymph node(s) are the first lymph nodes that are under the influence of tumour-derived factors and in which an immune response can be generated by the activation of naive T and B cells. Thus the state of the sentinel lymph node microenvironment is critical in the initial decision between activation and suppression of the immune system by the primary tumour. A better understanding of the microenvironment of the cervical sentinel lymph node is therefore critical for the development of new immunotherapeutic strategies. Also non sentinel lymph node(s) can be influenced in their

microenvironment, due to draining tumour derived factors from the SLNs.

Study objective

The primary objective of this study is to analyse the microenvironment of the primary tumour and sentinel and non-sentinel lymph node(s) (i.e. various T-cell populations, antigen presenting cells and myeloid-derived suppressor cells) in patients with cervical carcinoma.
The secondary objectives of this study are to assess the differences of the microenvironment in tumour-negative and metastatic sentinel lymph node(s).
Exploratory objectives of this study are to analyse the differences in microenvironment in (sentinel) lymph nodes and to analyse the difference in the (sentinel) lymph nodes compared to the primary tumour. Also, the systemic immunity will be determined by the analysis of the peripheral blood in patients with cervical cancer.

Study design

This is an exploratory study to further delineate the microenvironment of the primary tumour and (sentinel) lymph nodes in cervical cancer.

Study burden and risks

The isolation of lymph node cell samples via scrapings of the longitudinal cutting edges of lymph nodes that are processed for diagnosis may carry a very small risk for a false-negative diagnosis for the presence of metastases in lymph nodes because a little bit of lymph node material is removed before the lymph node is processed according to standard procedures. Notably, a surgically dissected lymph node is cut through the longitudinal axis as part of the standard procedures in the department of Pathology. Then the lymph node is paraffin embedded. From each half only one section is taken for diagnosis. The section used for diagnosis follows the cutting of several sections, a procedure which is needed to have an optimal section cut off the embedded lymph node. It should be appreciated that there is always loss of lymph node material before a diagnosis can be made. Also in case of a sentinel lymph node procedure only a few sections are used for diagnosis. This indicates that there will always be a small risk for a false negative diagnosis. The department of Pathology considers the chance of missing a metastasis in a lymph node by introduction of scraping the cutting edge of the lymph nodes very small, but they cannot exclude it. There are no direct benefits for participating patiënts.

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

In case of a lymph node debulking, a small tumour biopsy will be performed on the surgery room. This carries a small risk of infection/bleeding, but as the

patient will be hospitalized for a couple of days, this can be adequately monitored and/or treated.

When injecting patent blue into the tumor for detecting sentinel lymph node(s) there is a very small change for the patiënt to develop an allergic reaction (1-2%)..

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 < 18 years at start of the study;
Patients with cervical cancer other than squamous-, adeno- or adenosquamous- origin.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-06-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	16-02-2018
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL62567.031.17
Other	NTRcode volgt