Pilot study to evaluate the potential of growing out tumor infiltrating lymphocytes from cervical carcinoma

Published: 23-02-2023
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This study aims to evaluate the potential of growing out TIL from several patients with cervical carcinoma.

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

Summary

ID

NL-OMON53901

Source
ToetsingOnline

Brief title
TIL study cervical carcinoma

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Cervical carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Geen extra kosten verbonden aan deze studie

Intervention

Keyword: Cervical carcinoma, Tumor infiltrating lymphocytes

Outcome measures

Primary outcome

• To collect malignant (primary tumor or metastases) tissue from patients with

cervical carcinoma.

• To set up a TIL culture protocol for cervical carcinoma, resulting in a TIL

product with sufficient cell numbers for adoptive T cell therapy

• To evaluate potency of the TIL product through reactivity assays

Secondary outcome

not applicable

Study description

Background summary

The presence of intratumoral immune cells and in particular CD8 (cytotoxic) T cells has been associated with favorable prognosis in several malignancies including melanoma, ovarian cancer and colorectal cancer. These observations have in large part inspired the development of adoptive T cell therapy with tumor infiltrating lymphocytes (TIL) as the treatment modality for metastasized disease, often using melanoma as a platform. Previous clinical trials in melanoma patients have achieved clinical responses in approximately 50% of stage IV melanoma patients.
Importantly, thus far, melanoma remains the only disease for which TIL therapy has reproducibly shown these results. The goal to expand TIL treatment to other entities besides melanoma is one of the pillars of the business case for cell therapy. Cervical carcinoma is an attractive candidate as almost all (estimated around 95%) of the tumors are Human Papilloma Virus (HPV) related tumors. Previous clinical trials in cervical cancer patients have showed objective response rates (ORR) ranging from 25%-44% with TIL therapy. Therefore, we want to expand the TIL therapy program to this entity as well.

Study objective

This study aims to evaluate the potential of growing out TIL from several patients with cervical carcinoma.

Study design

This is a pilot study where patient material will be collected and utilized for translational research purposes.

Intervention

not applicable

Study burden and risks

The expected risks or side*effects of taking additional biopsies are low. Nevertheless, there is a small chance for complications in the form of infection or bleeding. Standard procedures will be followed in case any of these complications occur, to ensure the safety of the patient.

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

• Histologically proven cervical carcinoma of at least FIGO 2018 stage IB1
• Age above 18 years
• Patients must have an indication for routine investigation or treatment under general anesthesia during which tumor material can be obtained
• Able to provide written informed consent

Exclusion criteria

• History of bleeding disorders

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):	26-06-2023
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	23-02-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-05-2024
Application type:	Amendment
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	NL82622.041.22