POLE EC pilot study: Identification of neo-antigen specific immunity in POLE-mutant endometrial cancer

Published: 11-12-2017
Last updated: 12-04-2024

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

Summary

ID

NL-OMON44597

Source
ToetsingOnline

Brief title
POLE-EC001

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cancer of the womb, uterine cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Jan Kornelis de Cock stichting

Intervention

Keyword: Endometrial cancer, Immunity, Neo-antigens, T-cells

Outcome measures

Primary outcome

Detection of neo-antigen specific cellular immunity in POLE-mutant endometrial

cancer patients.

Secondary outcome

None

Study description

Background summary

In 2013, a new molecular classification of endometrial cancers was proposed. One of the novel subgroups defined in this molecular classification comprises patients harboring a somatic mutation in the exonuclease domain of POLE. These POLE mutated ECs have been characterized as having an ultramutated phenotype and are associated with a favorable clinical outcome compared to other molecular subgroups.

Recently, we, and others, have demonstrated high numbers of predicted immunogenic mutations and enhanced anti-tumor immune responses in ultramutated POLE-mutant ECs; data which may provide insight into the favorable survival of this group of patients. A logical next step in understanding the differences in immune responses between the four molecular subgroups in EC would therefore be the direct identification and quantification of tumor-specific T-cells targeting neo-antigens within POLE-mutant endometrial cancer.

Study objective

The purpose of this project is to investigate the presence and course of neo-antigen specific immunity in patients with polymerase epsilon (POLE) mutated endometrial cancer, with the intent to exploit the obtained knowledge of neo-antigen specific immunity for the development of neo-antigen specific adoptive T-cell transfer therapy for this disease entity.

Study design

Pilot study

Study burden and risks

The risk of participation is considered minimal, as participation consists of a venepuncture. Patients will not benefit from participation in the study. The ultimate goal of this study is to develop immunotherapy for endometrial cancer in order to improve disease free survival and reduce the need for other adjuvant therapies such as radiation and chemotherapy in a selected group of patients. To this end it is necessary to gain further insight into natural immune responses to specific tumour neo-antigens in POLE-mutated endometrial cancer patients.

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

- Women with POLE mutated endometrial cancer
- Adequate venous access for blood collection
- 18 years of age or older
- Availability of tumour digest in biobank
- Informed consent

Exclusion criteria

- Previous or concurrent malignancy
- Current treatment with immunosuppressive therapy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2018
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	11-12-2017
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-04-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL61850.042.17