Investigation of Natural WT1-specific and PRAME-specific Immunity in Ovarian Cancer

Published: 22-04-2013
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Rationale: The purpose of this project is to investigate the presence and course of natural WT1-specific and PRAME-specific immunity in EOC patients, with the intent to exploit the obtained knowledge of WT1-specific and PRAME-specific immunity for...

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

Summary

ID

NL-OMON40116

Source
ToetsingOnline

Brief title
WT1 and PRAME immunity in ovarian cancer

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: KWF stipendium voor gepromoveerde arts-assistent

Intervention

Keyword: Immunotherapy, Ovarian Cancer, Tumor antigens

Outcome measures

Primary outcome

Quantification and qualitative analysis of WT1-specific and PRAME-specific

cellular and humoral immunity in patients with EOC during standard therapy.

Secondary outcome

NA

Study description

Background summary

Evidence of involvement of the immune system in epithelial ovarian cancer (EOC) is widely available. In an attempt to exploit the immune system to improve prognosis of this disease, immunotherapy is under development. To this end, it is pivotal to understand what targets the immune system uses for its anti-tumor responses. Two possible targets are WT1 and PRAME.

Study objective

Rationale: The purpose of this project is to investigate the presence and course of natural WT1-specific and PRAME-specific immunity in EOC patients, with the intent to exploit the obtained knowledge of WT1-specific and PRAME-specific immunity for the development of WT1-specific and/or PRAME-specific immunotherapy for this disease entity.

Specific objectives:
1. detection of WT1-specific and PRAME-specific immunity in patients with EOC
2. determination of the effect of standard therapy on WT1-specific and PRAME-specific immunity
3. determination of the optimal timing of leukapheresis for further development of WT1-specific and/or PRAME-specific adoptive T-cell transfer therapy.

Study design

prospective observational study

Study burden and risks

Participants will be asked to give three blood samples during their normal diagnostic and therapeutic work-up. The first sample will be obtained prior to start of therapy (220 ml), the second sample will be obtained after the third course of chemotherapy (60 ml), the last sample will be obtained 4 weeks after completion of therapy (220 ml). Patients who are referred to the University Medical Center Groningen for cytoreductive surgery who have already received three cycles of neoadjuvant chemotherapy will also be included. Therefore the first sample (220ml) will be skipped, the second and last samples will be obtained according to the protocol, respectively after the third cycle of chemotherapy (60 ml), and 4 weeks after completion of therapy (220 ml). Blood collections will be combined with regular hospital visits and when possible with routine venapunction for diagnostic purposes. Risk of participation is considered minimal as ordinary venapunction will be performed. Patients will not benefit from participation in the study. The ultimate goal of this study is to aid the development of immunotherapy for ovarian cancer. To this end it is necessary to gain further insight into natural immune responses to tumour antigens in patients with epithelial ovarian cancer.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- women newly diagnosed with epithelial ovarian cancer; prior to treatment or after neoadjuvant chemotherapy prior to cytoreductive surgery
- adequate venous access for blood collection
- 18 years of age or older
- informed consent

Exclusion criteria

- previous or concurrent malignancies, other than basal or planocellular cancer of the skin
- concurrent immunosuppressive therapy, other than chemotherapy for ovarian cancer
- recurrent epithelial ovarian cancer

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2013
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-10-2014
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	NL42448.042.12