Tumor- derived vesicles as Biomarkers for Ovarian cancer

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Objective: The aim of this study is to investigate the potential role of microvesicles as novel biomarkers for ovarian cancer and to asses if their presence and characteristics are related to stage and prognosis.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON37442

Source
ToetsingOnline

Brief title
TBO study

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biomarkers, Microvesicles, Ovarian cancer

Outcome measures

Primary outcome

This project concerns the relevance of vesicles in ovarian cancer as potential biomarkers and can be subdivided in the following research sections:

1) Microparticles and exosomes will be isolated from urine, ascites and blood and identified on basis of their size, density and ability to bind cell specific antibodies. This will be measured by the use of a flow cytometer. Microvesicles presence and characteristics will be analysed and compared with those of healthy volunteers.

2) The presence of different proteins will be analysed within the isolated microvesicles and in the remaining supernatant. Different immunostaining techniques will be applied, such as western blots, flow cytometer and ELISpot. We will compare protein expression pattern from vesicles from patients with ovarian cancer and healthy volunteers to explore the sensitivity (and specificity) of the potential markers.

Secondary outcome

3) Depending on these results, collected samples may be used to investigate genetic material which is captured in the microvesicles. Specific RNA sequences within isolated microparticles or exosomes will be analysed by use of reverse transcription polymerase chain reactions (RT-PCR). Other methods such as

micro-arrays may be used to further investigate microvesicle*s RNA and DNA.

Study description

Background summary

Rationale: Ovarian cancer is the sixth most common cancer affecting females and it is the most common cause of gynaecologic cancer- associated death. Advances in imaging techniques, surgical management, radiotherapy and chemotherapy have improved the outcome for patients. However for ovarian cancer, as for the most gynaecological cancers, the understanding of the cause and course at cellular level is incomplete. A possible relevant cellular mechanism is the formation of microvesicles such as microparticles (MP) and exosomes. Growing evidence suggests that vesicles released from cancer cells in gynaecological malignancies contribute to malignant behaviour. Moreover, tumour cell-derived exosomes have been suggested as diagnostic biomarkers. This study investigates the potential role of microvesicles in plasma, urine and ascites as novel biomarkers for ovarian cancer and asses if their presence and characteristics are related to disease stage and prognosis.

Study objective

Objective: The aim of this study is to investigate the potential role of microvesicles as novel biomarkers for ovarian cancer and to asses if their presence and characteristics are related to stage and prognosis.

Study design

Study design: This is an exploratory pilot study.

Study burden and risks

This study involves the use of blood samples, collection of a urine sample and collection of ascites. To minimize burden the taking of blood samples during this study will be combined with the routine investigations. One sample of midstream urine (small sterile container; 30ml) will be collected from each patient or healthy volunteer. Ascites fluid will only be collected when a ascites tap is performed for diagnostic purposes or symptom relieve. The majority of the fluid will be discarded. A small sample of this material will be used for research. There are no direct benefits for participating subjects.

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

Material from 30 patients diagnosed with ovarian cancer and samples from 30 healthy volunteers will be collected. ;Inclusion criteria for the two groups;1. Patients with ovarian cancer: ;a. Diagnosed with epithelial ovarian cancer
b. > 18 years
c. Treatment in VUMC
d. Understanding of the Dutch or English language
e. Not using any medication
f. No thrombotic events in history
g. Written informed consent ;2. Healthy volunteers: ;a. > 18 years
b. Understanding of the Dutch or English language
c. Not using any medication
d. No malignancies in past

e. No thrombotic events in history
f. Written informed consent

Exclusion criteria

1. Patients with ovarian cancer: ;a. < 18 years
b. No understanding of the Dutch or English language
c. Patients with history of malignancy other than that of ovarian cancer
d. Use of medication
e. Thrombotic events in history
f. No written informed consent ;2. Healthy volunteers: ;a. < 18 years
b. No understanding of the Dutch or English language
c. Use of medication
d. Malignancies in past
e. Thrombotic events in history
f. No written informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-09-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL38580.029.12