Tumour educated platelets in the (early) diagnosis of ovarian cancer.

Published: 06-04-2017
Last updated: 18-07-2024

Primary objective:To distinguish benign ovarium lesions from early cancer lesions, based upon their platelet RNA profile. Secondary objectives:* Evaluate the diagnostic accuracy of platelet RNA profiling in detecting early-stage ovarium cancer...

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

Summary

ID

NL-OMON50501

Source
ToetsingOnline

Brief title
TEP's in ovarian cancer

Condition

- Reproductive neoplasms female malignant and unspecified
- Obstetric and gynaecological therapeutic procedures

Synonym
cancer of the ovary, Ovarian cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diagnostics, Ovarian cancer, Tumour educated platelets

Outcome measures

Primary outcome

The difference in blood platelet RNA profile between ovarium cancer and benign

ovarium lesions.

Secondary outcome

none

Study description

Background summary

Cancer is primarily diagnosed by clinical presentation, imaging and pathological analysis of tissue biopsies, increasingly supported by molecular diagnostics tests. However,
late diagnosis and misdiagnosis due to limitations of tissue biopsy acquisition remains a major problem. Therefore, a general blood test to pinpoint cancer early and adequately can be considered the *Holy Grail*, because diagnosis in an earlier stage significantly improves the chance of cure from cancer. Several blood-based biosources are currently being evaluated as liquid biopsies, including cell-free DNA and circulating tumor cells, but none of these have been implemented for primary (multiclass) cancer diagnostics. Tumor-educated platelets (TEPs) can function as potential blood-based biosource for (early) cancer diagnostics. Blood platelets - the second most-abundant cell type in our blood - are implicated in hemostasis and wound healing. Platelets have recently emerged as central players and immediate responders in the systemic and local responses to tumor growth. Confrontation of platelets by tumor cells via transfer of tumor-associated biomolecules (*education*) results in the sequestration of these biomolecules (derived from both tumor and its micro-environment), causing a distinct platelet mRNA profile. We have previously shown that platelets acquire glioblastoma and prostate cancer mRNA biomarkers and that glioblastoma TEP mRNA profiles harbour diagnostic potential.

Study objective

Primary objective:

To distinguish benign ovarium lesions from early cancer lesions, based upon their platelet RNA profile.

Secondary objectives:

* Evaluate the diagnostic accuracy of platelet RNA profiling in detecting early-stage ovarium cancer compared to healthy controls;
* Evaluate the diagnostic accuracy of platelet RNA profiling in detecting early-stage ovarium cancer compared to stage IV ovarium cancer;
* Evaluate the accuracy of platelet RNA profiling in differentiating between ovarium cancer and other tumor types.

Study design

Observational study (cohort)

Study burden and risks

None

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Surgery becasuse of ovarian mass and/or surgery becasue of suspician of ovarian cancer

Exclusion criteria

Suffering from other malignancies than ovariancancer

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-12-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL58161.058.16