Early detection of ovarian cancer and response prediction: TEP and ctDNA study.

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Develop and evaluate the potential of TEPs and ctDNA as a novel liquid biomarker for early ovarium cancer diagnostics. And to evaluate the accuracy of ctNDA on response evaluation in patients with ovarian carcinoma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON50170

Source
ToetsingOnline

Brief title
TEP ctDNA study

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
ovarian tumor, ovarium cancer

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: ctDNA analysis, detection, ovariumcancer, platelet RNA profiling, therapy respons

Outcome measures

Primary outcome

To distinguish benign ovarium lesions from early cancer lesions, based upon

their ctDNA en platelet RNA profile.

To evaluate the accuracy of prediction response of ovarian carinomas on

therapy.

Secondary outcome

Evaluate the diagnostic accuracy of ctDNA and platelet RNA profiling in

detecting early-stage ovarium cancer compared to healthy controls;

Evaluate the diagnostic accuracy of ctDNA and platelet RNA profiling in

detecting early-stage ovarium cancer compared to stage IV ovarium cancer;

Evaluate the accuracy of ctDNA and platelet RNA profiling in differentiating

between ovarium cancer and other tumor types.

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. A landmark paper in Science has recently shown that, by combining analysis of ctDNA and protein tumor markers, depending on the tumor type, sensitivities of between 50 and 100% (nearly 100% sensitivity for FIGS. 1 to III ovarian carcinoma) are achieved. to show tumors, which can be treated curatively with an operation. The specificity was at least 99% for each tumor type (Cohen et al Science 2018).

The Catharina Kanker Institute (CKI) has already gained experience in the use of liquid biopsy. A clinical study has been in progress for a year and a half with patients suspected of lung cancer. In addition to the standard studies, material for analysis of circulating tumor DNA (ctDNA) and protein tumor markers is taken from these patients. For the analysis of ctDNA is recent, d.m. an external subsidy, a PCR device suitable for the sensitive detection of ctDNA in plasma. A first spin-off of this scientific research will be introduced in routine diagnostics around the summer
This amendment request relates to the addition of protein tumor markers and of circulating DNA as a liquid diagnostic to the TEP study. For this purpose, an 8 ml EDTA and 4 ml solid blood should be taken from this test subject population, in addition to the 4 ml EDTA tube.
analysis
With the material obtained prospectively the clinical value of ctDNA analysis and protein tumor markers will be determined when diagnosing ovarian carcinoma, differentiation and treatment of this and monitoring the course of the therapy.

Study objective

Develop and evaluate the potential of TEPs and ctDNA as a novel liquid biomarker for early ovarium cancer diagnostics. And to evaluate the accuracy of ctNDA on response evaluation in patients with ovarian carcinoma.

Study design

Multicenter, Investigator-initiated, observational study

Study burden and risks

There is no extra burden/risk for the patients in this study. There will collect 1-3 x 3 veils of blood during a clinical blood withdrawal.

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

Patients who are suspected of having ovarian cancer, patients who are diagnosed with ovarian cancer, and patients with ovarian cysts of which it is unknown whether it is benign or malignant and who receive either surgery with definitive pathology or follow up.

Exclusion criteria

Woman diagnosed with any type of cancer besides ovarian cancer.
Previous intra-abdominal malignancies in the history

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	11-04-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	18-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL68037.100.18

Study results

Results posted: 04-07-2023

First publication
01-01-1900