

Subcellular components and multi-drug resistance in epithelial ovarian carcinoma

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

Summary

ID

NL-OMON41885

Source

ToetsingOnline

Brief title

SCP&MDR

Condition

- Reproductive neoplasms female malignant and unspecified
- Ovarian and fallopian tube disorders

Synonym

ovarian cancer, Ovarian carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: European Cancer Center

Intervention

Keyword: Chemotherapy resistance, Epithelial ovarian carcinoma, Subcellular components

Outcome measures

Primary outcome

In this protocol, various parameters are to be distinguished:

- Differences in concentration of ctDNA copy numbers and specific DNA fragments in EOC, EOC responding adequately to chemotherapy and EOC with chemotherapy resistance.
- Differences in concentration of miRNA and specific miRNAs in EOC, EOC responding adequately to chemotherapy and EOC with chemotherapy resistance.
- Differences in concentration and characteristics of EVs from patients with EOC, EOC responding adequately to chemotherapy and EOC with chemotherapy resistance.

Secondary outcome

Not applicable.

Study description

Background summary

Standard care for advanced epithelial ovarian carcinoma (EOC) comprises cytoreductive surgery in combination with platinum and taxane based chemotherapy. Although initially, chemotherapy yields response rates of more than 80%, platinum-resistance is frequently seen in recurrent disease, especially in patients with recurrence within 6 months after initial treatment. Prediction of chemosensitivity could prevent unnecessary harmful treatment, with accompanying side-effects. Recent years, the importance of the influence of tumour derived subcellular particles, like circulating tumour DNA (ctDNA), microRNA (miRNA) and extracellular vesicles (EVs), on chemotherapy resistance has been increasingly recognised. Knowledge of these subcellular particles is a

prerequisite for understanding tumour behaviour during treatment and progression.

Study objective

The purpose of this study is to investigate the characteristics of different sub cellular constituents in different body fluids of patients with advanced EOC with different histotypes. Besides obtaining more clarity about the role of these subcellular particles in chemoresistance, we attempt to identify new biomarkers for early detection of drug resistance.

Study design

Following informed consent, plasma and urine, and if possible ascites, will be collected during presentation and follow-up in the outpatient clinic. ctDNA, miRNA and EVs will be labeled and analysed by flowcytometry, TEM, Tam-Seq, Taqman miRNA assays and PCR analysis.

Study burden and risks

Not applicable.

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 with untreated epithelial ovarian cancer, stage III or IV.

Exclusion criteria

Patients deprived from ability to decide for participation on her own

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 22-12-2014

Enrollment: 75

Type: Anticipated

Ethics review

Approved WMO

Date: 05-02-2015

Application type: First submission

Review commission: METC NedMec

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	NL50907.031.14