# 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

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### 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

Public

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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
Туре:	Anticipated

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# **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** CCMO **ID** NL50907.031.14