Towards molecular characterization of sporadic epithelial ovarian carcinoma

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

Summary

ID

NL-OMON38084

Source
ToetsingOnline

Brief title
ORCA (OvaRian CAncer research)

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF (indien gehonoreerd)

Intervention

Keyword: biobank, ovarium carcinoma, proteomics, RNA sequencing

Outcome measures

Primary outcome

By combining techniques and apllying them to the same large series of patients, we aim to fully describe the characteristics of ovarian carcinomas that determine whether or not a patient reponds well to her treatment. We hope to be able to discriminate subclasses of ovarian cancer that offer leads for novel therapeutic approaches. By using the infrastructure of the cooperation that has been set up between the various medical centers we will set up new pospective clinical trials for the treatment of ovarian cancer based on the protein and genetic information generated by our studies.

Secondary outcome

Not applicable.

Study description

Background summary

All patients with advanced ovarian carcinoma are treated with a combination of extensive debulking surgery and chemotherapy. Despite a good initial response rate, most patients will develop progression of disease with a 5-year survival of less than 30%. At present, we are not able to determine the optimal surgical and/or chemotherapy regimen for an individual patient.
Comprehensive genomic studies of ovarian carcinoma have already identified molecular abnormalities that affect outcome of the disease or could be targets to guide therapy. However, although various pathways have been described that play an important role in ovarian cancer, it is still not known which pathways are most important for survival or how they could be influenced to improve the response to treatment. It has been suggested that the different histological subtypes of ovarian cancer have specific characteristics and this may have a

possible relation with different sensitivity to chemotherapeutic treatment. However, reports are contradictory and no new treatment regimens have resulted from this work so far.

Study objective

The aim of the present study is to identify aberrations that play a significant role in therapy response of ovarian cancer patients. RNA sequence/expression and protein expression data will be combined and correlated to the extensive clinical follow-up of our large patient cohort in order to elucidate the most relevant pathways in carcinogenesis and response to therapy, and to uncover whether post-transcriptional regulation plays a role in these processes. Detailed knowledge of the transcriptome and proteome involved in carcinogenesis and progression of ovarian carcinoma will help to classify subgroups that differ in treatment response, like the ability to undergo optimal debulking surgery, response to chemotherapy and survival. Based on the results clinical trials for individualizing treatment of ovarian cancer patients will be set up.

Study design

We plan to conduct a comprehensive study on our cohort of ovarian cancer patients of whom all relevant information is known and who received treatment according to standardized treatment protocols and of whom tumor tissue is available. In addition to convantional techniques, we will use to relatively new techniques to fully characterize ovarian carcinomas.
Using RNA sequencing (RNA-Seq) we will measure mRNA levels, study mutations, and monitor the presence of non-coding RNAs in defined tumor tissues of various histological subtypes.We aim to identify genes that differ between patients who repond either very well or on the other hand poorly to treatment and who showed recurrent disease quickly. Since the behaviour of the tumor will primarily be determined by the proteins that the genes eventually code for, we subsequently measure protein expression by a new and powerful mass spectrometry approach called MSE. This approach is able to accurately identify and quantify hundreds of proteins and is a leap forward in protein analysis technology.

Study burden and risks

The burden consists of a maximum of 5 minutes of the patient's time for the withdrawal of extra blood.

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

Women with an ovarian carcinoma, all histological subtypes and all stages and grades will be included. Approximately 300 new patients suspected of ovarian cancer are expected each year within the CGOA (AMC, AvL/NKI, VUmc), of whom 100 are expected to be diagnosed with a benign ovarian tumour, and 200 with a malignant ovarian tumour.

Exclusion criteria

Women with an expected benign ovarian tumour.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2012
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	02-10-2012
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	NL29474.018.12