Predict Response Of Drugs In Ovarian Cancer Treatment Using Organoids

Published: 06-02-2024
Last updated: 02-12-2024

To determine prospectively the correlation between in vitro patient-derived organoid response and progression-free survival.

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

Summary

ID

NL-OMON56484

Source
ToetsingOnline

Brief title
PRODICT

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
epithelial ovariancarcinoma, ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Gieskes Strijbis Fonds en Teuny van Wijgerden Fonds en eerste geldstroom UMCU gynaecologische oncologie

Intervention

Keyword: chemotherapy, organoids, ovarian cancer, prodict

Outcome measures

Primary outcome

Progression-free survival.

Secondary outcome

• Response at first, second, and/or following evaluations after treatment with standard-of-care drugs as measured by the change in tumor size on a CT scan (continuous variable)

• Response at patient level according to RECIST 1.1 (categorical variable)

• Response at patient level according to CA-125 levels (continuous variable)

• Assess above mentioned end-points per specified subgroups:

o per treatment line (platinum-naïve, platinum-sensitive, or platinum-resistance)

o per histopathological subtype (high-grade serous or others)

o per type of treatment given (carboplatin-paclitaxel with or without PARPi or bevacizumab maintenance therapy, carboplatin-gemcitabine with or without PARPi or bevacizumab maintenance therapy, weekly paclitaxel, etoposide,liposomal doxorubicin or early clinical trial compound).

• Yield/feasibility of organoid culture and tumor cell line (2D) culture

Study description

Background summary

Epithelial ovarian carcinoma (EOC) is a highly lethal gynecological malignancy often diagnosed at an advanced stage, resulting in low survival rates. Current treatment strategies include debulking surgery and platinum-based chemotherapy. Primary and acquired chemoresistance leading to treatment failure and high recurrence rates remain significant challenges. This study aims to address these issues by using patient-derived organoids (PDOs) to predict treatment response.

Study objective

To determine prospectively the correlation between in vitro patient-derived organoid response and progression-free survival.

Study design

A unicenter observational cohort study from March 2024 until July 2027. Tumor tissue from diagnostic biopsies, debulking surgeries, and/or ascites drainage will be collected for organoid culture. In vitro organoid responses to treatment will be compared to clinical treatment outcomes.

Study burden and risks

Extensive experience exists with performing debulking surgeries, diagnostic biopsies, and ascites drainage in patients with EOC, and these procedures are considered to be safe and an essential part of standard of care. Trial participation is not expected to offer significant patients benefit.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

To be eligible to participate in this study, a subject must meet all of the following criteria:

1. Patients diagnosed with (the suspicion of) epithelial ovarian carcinoma amenable for standard-of-care systemic treatment in the adjuvant or recurrent setting, including, but not limited to:
Treatment for primary advanced stage EOC:
1.1. Carboplatin/paclitaxel + PARP inhibitor* (including repeated cycles)
1.2. Carboplatin/gemcitabine + PARP inhibitor* (only if not administered yet)
1.3. Carboplatin/gemcitabine + bevacizumab (including repeated cycles)

Treatment for recurrent advanced stage EOC:
1.4. Paclitaxel (weekly) +/- bevacizumab
1.5. Etoposide
1.6. Liposomal doxorubicin
1.7. Early phase clinical trial compound(s)
1.8. Treatments outside the above-mentioned standard-of-care regimens can be considered but must be approved by the study*s P.I. before including patients.

* PARP inhibitors incl.: registered olaparib, niraparib and rucaparib.
Talazoparib and veliparib are still under investigation in clinical trials.

2. Patients age >=18 years, willing and able to comply with the protocol as judged by the investigator with a signed informed consent.

3. Patients with neoadjuvant treatment or recurrent disease must have radiographically evaluable disease, either measurable or non-measurable per RECIST 1.1, as assessed by the local site investigator/radiology.

Patients starting a new line of treatment after participation in this trial are

eligible to participate again. Informed consent, baseline screening, and the diagnostic biopsy procedure must be repeated.

Exclusion criteria

• Patients with unrelated secondary tumors that in the opinion of the investigator interfere with treatment decision making, affect response evaluation of pose a competing risk for survival.
• Patients who underwent a diagnostic biopsy due to suspicion of EOC, but histological examination did not confirm this diagnosis.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-04-2024
Enrollment:	239
Type:	Actual

Ethics review

Approved WMO

Date:	06-02-2024
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	NL85296.041.23