Archipelago of Ovarian Cancer Research

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26124

Source
Nationaal Trial Register

Brief title
AOCR

Health condition

Ovarian cancer, Fallopian tube cancer and primary peritoneal cancer.

Sponsors and support

Primary sponsor: Dutch Cancer Society
Source(s) of monetary or material Support: The Dutch Cancer Society provided funding for setting up the biobank for four years. After that, the Archipelago infrastructure, including biobank, should be self-sustainable. Covering of costs will come from external parties who request issue and/or collection of biomaterials and from incorporation of biobanking costs in future grant proposals.

Intervention

Outcome measures

Primary outcome

Improved diagnostics, treatment and survival

Secondary outcome

Identification of predictive and prognostic factors

Study description

Background summary

Ovarian cancer is diagnosed in approximately 1400 women annually in the Netherlands. Over the last years, treatment of Dutch ovarian cancer patients has been centralized into eight Centres for Gynaecologic Oncology (CGOs). Surgery is performed in 19 hospitals and is always supervised by a gynaecological oncologist. Despite this centralization of care, new surgical techniques and new systemic therapies, the 10-year overall survival rate of women with ovarian cancer is approximately 23% and has hardly improved over the last decades.

Scientific clinical collaboration takes place within the DGOG (Dutch Gynaecological Oncology Group). Contrarily, fundamental and translational research are mostly carried out by the CGOs on institutional basis. The aim is to improve the care and survival for women with ovarian cancer by performing large-scale fundamental and translational research. This can be done after reaching structural collaboration, uniformity and overview resulting from the AOCR.

The main objective of this project is to set up a nationwide, multidisciplinary biobank named ‘Archipelago of Ovarian Cancer Research’ (AOCR), established by all 19 hospitals where surgery on ovarian cancer is performed. Harmonized biobanking and standardized pathological examining and reporting will lead to unique data sets, certainly in combination with immunohistochemical analyses and genomic data collected in view of specific studies. This platform will use pre-existing research infrastructures and collaborations in the Netherlands (IKNL/NKR, PALGA, Health-RI, SlideScore and DGOG). This will achieve an efficient start of the infrastructure and make sure scientific results will be translated to clinical practice rapidly.

Standardized methods for pathology diagnosis will be implemented in close collaboration with PALGA. Digital images of representative slides will be made available. To further optimize classification and to ensure high quality data, a standard for immunohistochemical and genomic analyses to complement standard methodology for cytological/histological diagnostics will be developed. In addition, an ovarian-specific pathologists’ panel will be set up that will digitally assess new ovarian cancer cases. It will also serve as a facility by offering revision of pathology reports, several standard immunocytochemical stainings and NGS analyses (mutations, methylation or Copy Number Aberrations) of which the resulting data can be requested by AOCR members.

After the completion of this project, a platform will be available in the Netherlands in which biomaterials are collected in a standardized way. Before researchers request issue of biomaterials and data, they can request inventory of the available biomaterials in combination with specific clinical characteristics. For clinical trials it will be possible to collect biomaterials via the developed infrastructure. Moreover, standardized methods for pathology

diagnosis are implemented and all new cases of ovarian cancer are digitally assessed by the pathologists' panel.
Overall, this platform will strongly improve the collaboration on and impact of scientific research on ovarian cancer in the Netherlands. Eventually, this platform will contribute to the improvement of diagnostics, counselling, personalised treatment, monitoring response to therapy, survival and quality of life of patients with ovarian cancer.

Study objective

Setting up a nationwide, interdisciplinary platform for ovarian cancer research, including a biobank, will contribute to enhanced collaboration in fundamental and translational research
• between disciplines;
• between Dutch hospitals;
• internationally.

Study design

Simultaneously with regular appointments as much as possible

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

• Suspected or diagnosed ovarian cancer, Fallopian tube cancer or primary peritoneal cancer;

• Age ≥16 years;
• Written informed consent.

Exclusion criteria

• Mental disabilities;
• Not able to understand the patient information.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2020
Enrollment:	32500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Researchers can request an inventory of the number of available biomaterials in combination with specific clinical characteristics. If the number of biomaterials is considered to be sufficient for the specific research question, a research protocol for issue of biomaterials and data can be submitted. The AOCR Scientific and Steering Committee will assess the research proposal. When approved, the biomaterials will be issued to the researcher. Clinical and pathological data will be obtained from the Netherlands Cancer Registry (NCR) and the Dutch Pathology Registry (PALGA) on a per-study basis. The intention is that all research data will flow back into the infrastructure. In that way analyses will not have to be performed multiple times, but instead the same (experimental) results can be used for several research projects.

Ethics review

Positive opinion

Date:	14-04-2020
Application type:	First submission

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
NTR-new	NL8524
Other	Biobank Review Committee of the Amsterdam University Medical Center (UMC), location Academic Medical Center (AMC) : 2019_272

Study results

Summary results
Not yet applicable