

activating the Immune response In ovarian cancer study

Published: 10-04-2024

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Investigating the function of monocytes and their precursor cells originating from circulation, bone marrow, and spleen in the context of ovarian cancer.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON56684

Source

ToetsingOnline

Brief title

ACTION study

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym

ovarian carcinoma; malignant ovarian tumors

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: immune response, ovarian carcinoma

Outcome measures

Primary outcome

Characterizing the immune status of ovarian carcinoma patients compared to cancer-free controls, with a focus on hematopoietic organs and the immune cells originating from them. This will be accomplished by assessing the transcriptional, epigenetic, and functional programming of circulating monocytes and myeloid precursor cells in OC.

Secondary outcome

none

Study description

Background summary

Ovarian cancer (ovarian carcinoma) is one of the most deadly forms of cancer, as the disease is often diagnosed only in a late stage. Standard therapy consists of (interval) debulking surgery followed by chemotherapy. Despite this aggressive treatment, the five-year survival rate is less than 30%. To improve outcomes for patients, it is important to understand the pathophysiology of ovarian carcinoma from a systemic perspective, with a particular focus on the role of immune cells, as there is an immunosuppressive status in ovarian carcinoma. Very little is known about the function of monocytes and their precursor cells originating from the blood, bone marrow, and spleen in ovarian carcinoma patients. A better understanding of these systemic processes will contribute to the development of new therapies for ovarian carcinoma patients.

Study objective

Investigating the function of monocytes and their precursor cells originating from circulation, bone marrow, and spleen in the context of ovarian cancer.

Study design

Researcher-initiated, single-center exploratory cross-sectional study at the

Catharina Hospital in Eindhoven.

Study burden and risks

The risks are limited and include the possibility of hematoma formation with both venipuncture and bone marrow aspiration, and in women undergoing debulking, a puncture of the spleen.

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

-Subjects should be at least 18 years old and mentally competent

-Newly diagnosed patients with ovarian carcinoma (OC) who go for primary

debulking surgery or patients with OC are scheduled for interval debulking
- Controls: women who undergo surgery for benign gynaecological conditions under general anaesthesia

Exclusion criteria

- Mentally incompetent
- Pregnant or breastfeeding
- Known inflammatory or infectious diseases or an immunosuppressive status
- Using medication interfering with the immune system
- Severe comorbidities: other active malignancy (except for basal cell carcinoma and other in situ carcinomas)
- Serious psychiatric pathology
- A self-reported alcohol consumption of >21 units per week
- Bleedings disorder
- History of splenectomy
- Not mastering the Dutch language

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	03-09-2024
Enrollment:	90
Type:	Actual

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 10-04-2024

Application type: First submission

Review commission: METC Maxima Medisch Centrum (Veldhoven)

Approved WMO

Date: 30-07-2024

Application type: Amendment

Review commission: METC Maxima Medisch Centrum (Veldhoven)

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

NL86399.015.24