OveRcoming immunosupprEssion aNd rebAlancing the Immune reSponSe in ovAriaN CancEr (RENAISSANCE) study

Published: 18-11-2024
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To assess the transcriptional, epigenetic and functional reprogramming of circulating and tissue (BM and spleen) monocytes and myeloid progenitor cells in the context of ovarian cancer.

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON57106

Source
ToetsingOnline

Brief title
RENAISSANCE 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: immuneresponse, ovarian carcinoma

Outcome measures

Primary outcome

Transcriptional, epigenetic and functional signature of circulating and tissue (BM and spleen) monocytes and myeloid progenitors of ovarian cancer patients compared to women with bening gynaecological disease undergoing surgery for this problem

Secondary outcome

none

Study description

Background summary

Ovarian cancer is one of the most lethal cancers in the world due to late stage disease at diagnosis. Standard therapy consists of (interval)debulking surgery and chemotherapy, which results in a five-year survival rate of only 30%. To improve the patient*s outcome it is important to understand the systemic pathophysiology of ovarian cancer, especially the role of immune cells herein. Monocytes and myeloid progenitor cells in the circulation, bone marrow (BM) and spleen can undergo transcriptional, epigenetic and functional reprogramming that may contribute to ovarian cancer pathophysiology. Unravelling these systemic processes will identify novel therapeutic targets for the treatment of ovarian cancer.

Study objective

To assess the transcriptional, epigenetic and functional reprogramming of circulating and tissue (BM and spleen) monocytes and myeloid progenitor cells in the context of ovarian cancer.

Study design

Investigator-initiated, single-center explorative cross-sectional study at the Catharina Hospital in Eindhoven.

Intervention

Assessing the in vitro effect of Beta-glucan, Lipopolysaccharide, Mifamurtide, Heat-killed Candida an Bacillus Calmette-Guérin on trained immunity in women with ovarian carcinoma and women with benign gynaecological disease undergoing surgery for this problem

Study burden and risks

The risks are low. A possible complication is haematoma after venapuncture, bonemarrow biopsy or spleen biopsy.

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

Patients with ovarian carcinoma undergoinig primary debulking

Patients with ovarian carcinoma undergoinig intervaldebulking

Patiens without a malignancy undergoing surgery for benign gynaecological conditions

Exclusion criteria

Known inflammatory or infectious diseases or an immunosuppressive status
Using medication interfering with the immune system

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-09-2024
Enrollment:	90
Type:	Anticipated

Medical products/devices used

Generic name:	Trained immunity assay

Registration:	No

Ethics review

Approved WMO Date:	18-11-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL84392.000.23