The Blood-Belly Barrier

Published: 26-05-2015
Last updated: 21-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41847

Source
ToetsingOnline

Brief title
Triple B

Condition

- Reproductive neoplasms female malignant and unspecified
- Ovarian and fallopian tube disorders

Synonym
epithelial ovarian cancer, Epithelial ovarian carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: European Cancer Center

Intervention

Keyword: Barrier function, Epithelial ovarian carcinoma, Micro-environment, Structure

peritoneum

Outcome measures

Primary outcome

1. Structural investigation of the peritoneum by histology and immunostaining of peritoneal components in EOC.

2. Investigation of the peritoneal micro-environment in EOC, by measurement of the quantity and characteristics of MPs and exosomes, excreted by mesothelial cells, and by measurement of cytokines with anti-angiogenic or proliferation inhibiting functions.

Secondary outcome

Not applicable

Study description

Background summary

Ovarian cancer is the most lethal gynaecologic cancer. Epithelial ovarian cancer (EOC) spreads through the abdominal cavity, with involvement of the peritoneum. Although this peritoneum of the abdominal wall is only a thin serous membrane, peritoneal tumour depositions are generally small and growth is superficial. Tumour growth through the peritoneum and invasion of the abdominal wall is rare. Furthermore, EOC often stays in the abdominal cavity. The specific intra-abdominal spreading pattern of EOC suggests a possible barrier function of the peritoneum against tumour invasion and expansion across the peritoneum. However, a full understanding of this barrier function in relation to EOC at structural and (sub)cellular level remains to be clarified. The role of the micro-environment of the peritoneum and the role of peritoneal cell-derived particles in ascites or plasma, such as microparticles (MPs) and exosomes, is largely unknown.

Study objective

The aim of this study is to investigate the structure and the biological behaviour of the peritoneum, in relation to the specific growth of EOC on the

peritoneum, in order to identify the component of the peritoneum that maintains the blood-belly-barrier.

Study design

Following informed consent, samples of peritoneum, plasma and ascites will be collected during cytoreductive surgery or exploratory laparotomy Haematoxylin and eosin staining and Elastica van Gieson staining will be carried out to identify structural components of the peritoneum. Micro-environmental components including MPs, exosomes and cytokines with anti-angiogenic or proliferation inhibiting functions are determined by flowcytometry, Transmission Electron Microscopy and Multiplex Immuno Analysis.

Intervention

During the planned surgery (regular treatment) a maximum of four samples of peritoneum (4mm2 each) will be collected. Two peritoneal samples will contain tumormaterial and two samples of peritoneum are macroscopic healthy. In addition, one tube of blood will be taken from an already placed infusion during surgery, and these two tubes will be ascites fluid collected from the abdominal fluid aspirated. All the patients material will be collected once during the scheduled surgery.

Study burden and risks

Not applicable

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

1. Patients with serous ovarian cancer, FIGO stage III or IV, undergoing cytoreductive surgery or,
2. Patients undergoing abdominal surgery for a benign ovarian mass (control group)

Exclusion criteria

Patients deprived from ability to decide for participation on her own
During surgery, it appears, collection of samples is associated with additional health risk

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):	01-06-2015
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	26-05-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-12-2022
Application type:	Amendment
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	NL51422.031.14