The role of surgery- induced inflammatory mediators in macrophage activation

Published: 17-04-2012
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To identify circulating mediators that are released after surgery and which are responsible for macrophage activation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON39271

Source
ToetsingOnline

Brief title
Surgery-induced macrophage activation

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colon cancer, Colorectal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colorectal cancer, Inflammatory mediators, Macrophages, Surgery

Outcome measures

Primary outcome

- Capacity of pre- per- and post operative plasma to activate macrophages in vitro. Endpoints are production of reactive oxygen species (ROS) and conversion of MTT to formazan (this allows to assess the viability of cells).

- Identification of the inflammatory factors released after surgery that are responsible for macrophage activation. Endpoints are decrease of ROS production and conversion of MTT in the presence of blocking agents against inflammatory mediators.

Secondary outcome

not applicable

Study description

Background summary

Metastases in CRC patients originate from tumor cells that have disseminated from the primary tumor, and either spread via the venous circulation, the lymphatics or directly into the peritoneal cavity. Under physiological circumstances, the process of metastases formation is highly inefficient, as disseminated tumor cells have a limited life span and are rapidly eliminated by the immune system. However, evidence that inflammatory responses as a result of surgical trauma enhance the risk of metastases development is accumulating. We previously demonstrated that post-operative plasma of rats, receiving peritoneal surgery enhances activation of macrophages. Because we additionally demonstrated that macrophage activation leads to endothelial damage and enhanced tumor cell adhesion in the liver, we hypothesize that surgery creates permissive circumstances for tumor cells to adhere in target organs and thereby

increase chances of metastatic development.

Study objective

To identify circulating mediators that are released after surgery and which are responsible for macrophage activation.

Study design

Prospective, observational pilot study.

Study burden and risks

The burden associated with participation consists of extra blood sampling (in total 24 ml) taken pre-, per- and postoperatively. Therapy will neither be delayed nor altered and no extra complications are expected.
Patients participating in this study will not directly benefit. However, obtained results may lead to novel per-operative therapeutic adjuvant strategies, which will help future patients.

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

Resection of primary colorectal carcinoma.

Exclusion criteria

Excisting infection: Crohn's disease or ulcerative colitis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2013
Enrollment:	9
Type:	Actual

Ethics review

Approved WMO

Date:	17-04-2012
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL36125.029.11