Intestinal microvascular alterations and cytokine kinetics following cytoreductive surgery with hyperthermic intraperitoneal chemotherapy

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Primary objective: To evaluate the expected increase of the Microvascular Flow Index perioperative using a SDF-imaging device and the systemic inflammatory response by measuring inflammation biomarkers.Secondary objective: To learn more about the...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON40837

Source
ToetsingOnline

Brief title
MACH-study

Condition

- Gastrointestinal therapeutic procedures

Synonym
gastrointestinal micorcirculation, gastrointestinal microvascularisation

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

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

Intervention

Keyword: cytokines, gastrointestinal surgery, HIPEC, microcirculation

Outcome measures

Primary outcome

To describe gastrointestinal microcirculation and cytokine kinetics (CRP, white blood cell, IL-6, IL-8, IL 10 and TNF-* levels) in blood samples during and after CS-HIPEC procedure.

Secondary outcome

Body (core) temperature, Cardiac output (CO), Stroke volume (SV), Stroke Volume Variation (SVV), these later parameters are automatically measured by the flow-trac/vigileo and thus only accesable when an arterial catherter is inserted.

Study description

Background summary

Cytoreductive Surgery (CS) with Hyperthermic IntraPEritoneal Chemotherapy (HIPEC) is associated with postoperative morbidity like abdominal sepsis. Postoperative levels of systemic inflammation biomarkers (cytokines) have been found to correlate with the magnitude of surgery. Pro- and anti-inflammatory cytokines, such as interleukin-6 (IL-6), IL-8 and Tumor Necrosis Factor-*, are crucial mediators in this process. Microcirculatory distress may form one of the earliest stages of sepsis progressing into multiple organ failure. Sidestream dark field (SDF) imaging is a promising, non-invasive method to visualize the microcirculation and assess the degree of microvascularisation. In previous studies, sublingually measured microvascular alterations in patients with severe sepsis have been shown to correlate with worse outcome. Clinical research on microcirculation has gained much interest in the last years. We hypothesize that an inflammatory response develops following CS-HIPEC. To our knowledge, no study has been performed to evaluate this

inflammatory response and the effects on the intestinal microcirculation during and after CS-HIPEC procedure.

Study objective

Primary objective: To evaluate the expected increase of the Microvascular Flow Index perioperative using a SDF-imaging device and the systemic inflammatory response by measuring inflammation biomarkers.
Secondary objective: To learn more about the pathogenesis of gastrointestinal microvascular alterations due to systemic inflammation. This knowledge may aid us to develop future intervention strategies, aimed at improving peripheral microvascular flow, which could be beneficial for patient outcome.

Study design

A prospective, single centre, observational, clinical study.

Study burden and risks

The extent of burden and risk associated with participation in this study is very limited. Using Sidestream Dark Field imaging during a laparotomy is a non-invasive technique requiring a minimal amount of time. Most serum samples can be collected from the intraoperative placed arterial line. For postoperative follow-up two venous punctures are needed to collect remaining blood samples. A venous puncture is a well known minimal invasive procedure with limited burden for the participants of this research.

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 > 18 years of age
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
Undergoing a CS-HIPEC procedure for colorectal carcinoma
Chemotherapeutic agent used for HIPEC is Mitomycin-C
Signed informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Age <18 years
* Atrial fibrillation (because of possible interference with FloTrac*/Vigileo* cardiac output monitor)
* Left ventricular ejection fraction *30%
* Serious pulmonary disease (resting pO2 <90% at room air)
* Renal failure (clearance <30 ml/min as calculated using the Modification of Diet in Renal Disease formula)
* Inadequate bone marrow function (ANC *1.5 x 109/L and/or platelet count * 100 x 109/L)
* Pre-existing liver failure (Serum bilirubin * 2 x ULN, and/or ALAT and ASAT * 3 x ULN or need for partial hepatectomy during CS
* History of auto-immune or chronic inflammatory disease and/or on immunomodulatory medication

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Sidestream Darkfield (SDF) imaging device: video microscope
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	06-08-2014
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	NL48369.100.14