Effect of omega-3 fatty acids on the perioperative immune response and erythrocyte function

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Our primary objective is to study the effect of perioperative intravenous supplementation of omega-3 fatty acids on the perioperative inflammatory response compared to a saline control in patients undergoing surgery for colon cancer.

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

Summary

ID

NL-OMON40544

Source
ToetsingOnline

Brief title
EMPIRE-study

Condition

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

Synonym
Colon cancer, large bowel cancer.

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar

Source(s) of monetary or material Support: deels Fresenius Kabi en deels eigen onderzoeksfonds.,Fresenius Medical Care

Intervention

Keyword: erythrocyte function, immune reaction, omega-3 fatty acids, perioperative

Outcome measures

Primary outcome

To study the effect of perioperative intravenous administration of omega-3 fatty acids on the immune response of patients undergoing laparoscopic surgery for colon cancer, by measuring the ex vivo production of pro-inflammatory cytokine IL-6 in LPS stimulated whole blood.

Secondary outcome

To study:

* The effect of intravenous omega-3 fatty acids on the production of TNF-* and IL-10 in ex vivo LPS stimulated whole blood.

* The effect of intravenous omega-3 fatty acids on erythrocyte function.

* The effect of intravenous omega-3 fatty acids on the in vivo systemic inflammatory response, including white blood cell count, C-reactive protein and cytokine levels in serum.

* The effect of intravenous omega-3 fatty acids on postoperative outcome.

* The effect of intravenous omega-3 fatty acids on cognition

Study description

Background summary

Ideally, the postoperative inflammatory response is part of a well orchestrated

mechanism that contributes to tissue healing and rapid recovery. An exaggerated uncontrolled inflammatory response, however may lead to catabolism, tissue damage and organ failure.
Omega-3 fatty acids may provide a means to alter cellular immune responses to the benefit of the patient. When omega-3 fatty acids are incorporated into membranes of inflammatory cells, they trigger intracellular signalling pathways that result in a less pro-inflammatory response. They modify gene and protein expression, modulate membrane protein activity and act as a reservoir for bioactive molecules. They also have a strong anti-inflammatory effect by mediating resolution of the inflammation. Furthermore, omega-3 fatty acids improve erythrocyte function, which is vital for an adequate microcirculation, tissue oxygenation and wound healing. Erythrocyte function can be assessed measuring erythrocyte deformability, osmotic resilience and aggregation.
We hypothesize that the perioperative administration of intravenous omega-3 fatty acids results in a rapid incorporation in immune cells and erythrocytes, thereby reducing the postoperative inflammatory response and improving erythrocyte function in patients undergoing colorectal surgery.

Study objective

Our primary objective is to study the effect of perioperative intravenous supplementation of omega-3 fatty acids on the perioperative inflammatory response compared to a saline control in patients undergoing surgery for colon cancer.

Study design

A randomized, double blind, placebo-controlled study at the Surgery Department of the Medical Centre Alkmaar.

Intervention

Omegaven-Fresenius, a 10% fish-oil emulsion containing the omega-3 fatty acids EPA and DHA. The dosage per infusion will be 2ml/kg, one infusion in 4 hours the evening before the operation, and one infusion in 4 hours de morning after the operation day.

Study burden and risks

Omega-3 fatty acids can safely be administrated up to 0.2 g/kg BW/day. The burden is related to the intravenous administration during two separate time courses of 4 hours and the extra venous blood samples that will be drawn. Possible risks are side effects of Omegaven and flebitis. The possible benefit of the study is related to the effect of omega-3 fatty acids.

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 (male or female) undergoing elective laparoscopic surgery for colon cancer
*Age between 55 and 85 years
*BMI between 20 and 35 kg/m2
*Written informed consent

Exclusion criteria

*Participation in or having participated in another clinical trial within the previous 3 months
*Indications for continuously use of anticoagulant medication and no possibility to stop these medication perioperatively, for example patients with an artificial heart valve
*Bleeding disorders, determined by medical history and laboratory tests of clotting indices

*Metastatic disease
*Cardiac or cerebral infarction within the last 6 months
*Current history of inflammatory or infectious disease
*The use of anti-inflammatory drugs
*The use of thyroid medication
*The use of fish oil products or fish consumption more than 2 times a week
Contra-indication(s) for the use of Omegaven.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2014
Enrollment:	44
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Omegaven
Generic name:	Omega-3 fatty acids
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-12-2014
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
EudraCT	EUCTR2013-003664-32-NL
CCMO	NL46230.029.13

Study results

Date completed: 17-05-2016

Actual enrolment: 44

Summary results
Trial is onging in other countries