The effect of upper gastrointestinal surgery on the acute systemic inflammatory response

Published: 27-05-2016 Last updated: 20-04-2024

To investigate the acute inflammatory response in patients undergoing oncological surgery in which the splenic nerve bundle is exposed.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON46239

Source ToetsingOnline

Brief title preSPLENIUS

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders
- Gastrointestinal therapeutic procedures

Synonym

immune response, inflammatory response

Research involving Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis Source(s) of monetary or material Support: GlaxoSmithKline

1 - The effect of upper gastrointestinal surgery on the acute systemic inflammatory \ldots 15-05-2025

Intervention

Keyword: Cytokines, Inflammation, Spleen, Upper gastrointestinal surgery

Outcome measures

Primary outcome

Mapping of the systemic inflammatory response, as measured by means of pro-inflammatory cytokines, protein and transcript expression. Cytometric bead array will be used to identify important pro-inflammatory cytokines, amongst which most likely TNF-alpha, interferon gamma and interleukins such as IL-1, IL-6, IL-8, and IL-10. These cytokines will be analyzed in more detail using assays such as Enzyme Linked ImmunoSorbent Assay (ELISA) and by means of Polymerase Chain Reaction (PCR) for transcript expression.

Secondary outcome

- the effect of ex vivo lipopolysaccharide (LPS) stimulations on the Toll-like

receptor (TLR) responses of monocytes in these patients.

- the effect on the local pro- and anti-inflammatory responses in splenic

tissue in patients undergoing pancreaticosplenectomy (RAMPS procedure).

- the presence of nerve fibres in the gastrosplenic ligament in patients

undergoing pancreaticosplenectomy or esophagectomy.

Study description

Background summary

An acute, increased inflammatory response after surgery is associated with the occurrence of postoperative complications. Furthermore, a chronic inflammation lies at the basis of diseases such as inflammatory bowel diseases (IBD) and rheumatoid arthritis (RA), for which a definite therapeutic therapy is still

2 - The effect of upper gastrointestinal surgery on the acute systemic inflammatory ... 15-05-2025

needed. In experimental studies, we showed that neurostimulation of sympathetic nerve fibres reduces both local and systemic inflammation in preclinical models of IBD. In a future study, we want to investigate the effects of stimulation of splenic nerve fibres on acute, systemic inflammation during oncological surgery in which the splenic nerve bundle is exposed as part of the procedure. However, the effect of the operational procedures and exposure of the splenic nerve on the acute inflammatory response is not well known.

Study objective

To investigate the acute inflammatory response in patients undergoing oncological surgery in which the splenic nerve bundle is exposed.

Study design

A pilot study, in which the acute inflammatory response is investigated during oncological surgery in which the splenic nerve bundle is exposed. No additional interventions will be performed.

Study burden and risks

Blood samples will be collected at several predefined moments in relation to the moment of incision. Splenic tissue samples will only be collected and analyzed in patients undergoing pancreaticosplenectomy, in which the spleen is removed as part of the procedure.

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

- Subjects who undergo elective surgery in which the splenic artery is exposed as part of the procedure

- Written informed consent
- Older than 18 years

Exclusion criteria

- Previous splenectomy
- Use of steroids 4 weeks prior to inclusion
- Use of immunosuppresive agents (e.g. methotrexate, biologicals)

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

NL

4 - The effect of upper gastrointestinal surgery on the acute systemic inflammatory ... 15-05-2025

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2016
Enrollment:	50
Туре:	Actual

Ethics review

Approved WMO	
Date:	27-05-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	24-04-2017
Application type:	Amendment
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 CCMO

ID NL56549.100.16