Vasa brevia

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28998

Source
Nationaal Trial Register

Brief title
Vasa brevia

Health condition

Reflux, surgery, antireflux, fundoplication, icg

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis, 's-Hertogenbosch, Netherlands
Source(s) of monetary or material Support: Initiator funded

Intervention

Outcome measures

Primary outcome

The main endpoint of this study is the observation of a perfusion defect in the spleen and/or gastric fundus. Possible observations are no perfusion defect, possible perfusion defect and definite perfusion defect in one or both organs.

Secondary outcome

The quality of the assessment of perfusion will be scored as adequate or inadequate.

Study description

Background summary

-

Study objective

This pilot study aims to report on the diagnostic value of indocyanine green and fluorescence laparoscopy on vascularization defects of the stomach and spleen during antireflux surgery. It is our hypothesis that many splenic and gastric infarctions occur without the surgeon noticing, and there may be a connection between postoperative pain and this infarction.

Study design

Visual inspection of fluorescence intensity as representation of perfusion, before and directly after ligation of the gastrosplenic ligament.

Intervention

The main endpoint of this study is the observation of a perfusion defect in the spleen and/or gastric fundus. This endpoint will be measured by visual inspection of the blood flow of the spleen and gastric fundus during surgery, as made possible by the indocyanine green. As a control measurement, a visual assessment will be performed both before and after ligation of the gastrosplenic ligament. Independent observations of the surgeon, assistant and researcher will be recorded.

Contacts

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Eligibility criteria

Inclusion criteria

- Age ≥18

- Objectively proven GERD (by gastroscopy, manometry, 24-hour pH and/or impedance monitoring)

- Written informed consent for study participation

Exclusion criteria

- Age <18

- Pregnancy

- Breastfeeding

- Achalasia

- Previous gastric surgery

- Previous esophageal surgery

- Inability to understand the Dutch language

- Inability to understand and/or fill in the informed consent form

- Adverse reactions to indocyanine green, sodium iodide or iodide

- Hyperthyroidism, thyroid adenoma

- Liver insufficiency

- Reduced kidney function as defined by a Glomerular Filtration Rate of < 40

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2018
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-06-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45909
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7071
NTR-old	NTR7269
CCMO	NL66435.028.18
OMON	NL-OMON45909

Study results