# Ligation of the gastrosplenic ligament during upper gastrointestinal surgery; Effect on splenic and gastric perfusion: pilot study

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal therapeutic procedures |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON45909

**Source**
ToetsingOnline

**Brief title**
Vasa brevia

### Condition

- Gastrointestinal therapeutic procedures

**Synonym**
Acid reflux, Reflux

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Jeroen Bosch Ziekenhuis

**Source(s) of monetary or material Support:** De maatschap draagt zorg voor de kosten van de gebruikte middelen.

## Intervention

**Keyword:** icg, reflux, surgery, vasa brevia

## Outcome measures

### Primary outcome

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. More information on this assessment will be provided in chapter 8.3. Independent observations of the surgeon, assistant and researcher will be recorded.

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

With the increasing incidence of therapy resistant gastro-esophageal reflux and increasingly frequent unwillingness of patients to be burdened by a lifelong PPI subscription, an increasing amount of patients undergo antireflux surgery. Many surgeons deem division of the gastrosplenic ligament necessary in antireflux surgery to facilitate the creation of an adequate fundoplication; ligating the ligament enables additional mobilization of the stomach. The need for this, however, is still subject of debate in recent literature. The gastrosplenic ligament connects the greater curvature of the stomach with the hilum of the spleen and contains the short gastric and left gastro-epiploic vessels. The short gastric vessels are part of the blood supply to both the superior pole of the spleen and the gastric fundus. Peripheral splenic arterial branches have little collateral circulation, thus ligating the short gastric vessels could result in an infarct. While partial infarction of the spleen in patients with chronic pain after antireflux surgery has a reported incidence of around 1%, the true incidence of infarction of either the gastric fundus or spleen is unknown. Since a splenic infarction has a large overlap in symptoms with the normal postoperative course of antireflux surgery, we suspect that infarction is underreported. Additionally, it is unclear if - and to what extent - postoperative pain is associated with the altered vascularization of the spleen or stomach.

Minimally invasive surgery has improved the postoperative recovery period to the point where postoperative pain is the main barrier for outpatient treatment. If postoperative pain can be linked to splenic or gastric infarction, this could be an argument to leave the gastrosplenic ligament intact if possible. To be able to sufficiently judge the effects of ligating the short gastric vessels, surgeons need adequate information on the incidence of the iatrogenic splenic infarction after fundoplication and its association with postoperative pain. This pilot feasibility study could provide the basis for a future larger cohort study.

**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.

Primary Objective:
- Determining the effect of ligating the short gastric vessels on the vascularization of the spleen and gastric fundus.

**Study design**

This monocenter prospective observational study aims to objectify the effect of ligating the short gastric vessels on arterial blood supply to the superior pole of the spleen and gastric fundus using fluorescence laparoscopic imaging.

This observational study will be conducted at the Jeroen Bosch Ziekenhuis in 's-Hertogenbosch, the Netherlands. Patients will be included during a six-month period and will be followed for 1 week to ascertain the absence of adverse events. No adverse events are expected to occur outside of the 24-hour postoperative window, since indocyanine green administration is the only intervention.

When a patient is referred to a participating surgeon for antireflux surgery, the surgeon will ensure that the indication for surgery is valid through detailed medical history, physical examination, upper endoscopy results, pH measurements, manometry, CT imaging or gastric scintigraphy. After receiving informed consent for surgical treatment, the surgeon will discuss inclusion in the study with the patient. The patient will receive study information from the researcher and receive sufficient time for consideration of participating in the study. Before surgery, the researcher ascertains that the patient is suitable for the trial. This means the patient meets all the inclusion criteria and does not meet any of the exclusion criteria. After informed consent is obtained by the researcher, the patient will be enrolled in the study.

After inclusion in the study, patients will undergo standard treatment including laparoscopic antireflux surgery. During surgery, the patient will be administered indocyanine green intravenously once before and once after ligating the short gastric vessels. With the use of the near-infrared fluorescence mode of the laparoscopic equipment tissue perfusion defects will be visually inspected.

**Study burden and risks**

Patients participating in this study will receive standard care and outpatient clinic follow-up. Daily practice in our clinic includes routine ligation of the gastrosplenic ligament during antireflux surgery, therefore the surgical procedure and follow-up protocol for study patients will be identical to the regular treatment, with the addition of the injection of indocyanine green. The additional risk for the patient is limited to the administration of indocyanine green through a peripheral IV. Indocyanine green is a diagnostic tool, approved for use in cardiac, liver and ocular perfusion imaging. Indocyanine green is best known for its use in assessing the hepatic function and measuring hepatic blood flow. In the last decade, the use of indocyanine green in gastro-intestinal surgery has greatly increased worldwide for a great variety of applications; its use in assessing the micro- and macrocirculation in contemporary experimental surgery is well established. Published use cases in gastro-intestinal surgery include assessing the level of anastomosis in gastro-intestinal surgery, identifying deviations from the normal vascular

anatomy in laparoscopic gastrectomy, determining the viability of the anastomosis after bowel resection and bile duct identification. Nausea, anaphylactoid or anaphylactic reactions have been described in very rare cases (less than 1 in 10.000, see SPC Verdye). The anaphylaxis-related mortality is estimated at 1 in 330.000, see SPC Verdye). Patients with an allergy to ingredients of indocyanine green will not be included in the study. The dose used in clinical practice (0.1-0.5mg/ml/kg) is well below the toxicity level reported in the SPC (see SPC Verdye). Indocyanine green is cleared quickly and exclusively by the liver after intravenous administration. Due to its serum half-life of only three minutes, no background fluorescence is detectable after approximately 15 minutes, which allows a second injection within the same procedure. Proving the feasibility of assessing perfusion of the gastric fundus and superior pole of the spleen in antireflux surgery will ultimately be of value in future research, determining the true incidence and clinical implications of infarctions after antireflux surgery. Additionally, these findings could provide new information for optimizing the surgical approach in the future and provide a basis for research on post-operative complaints.

# 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

- Age *18
- Objectively proven GERD (ie. by gastroscopy, manometry, 24-hour pH and/or impedance monitoring)
- Written informed consent for study participation

## Exclusion criteria

- 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 invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-12-2018 |
| Enrollment: | 10 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 31-10-2018 |
| Application type: | First submission |
| Review commission: | METC Brabant (Tilburg) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28998
Source: Nationaal Trial Register
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL66435.028.18 |
| OMON | NL-OMON28998 |