Feasibility of Splenic Nerve Stimulation During Esophagectomy

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Evaluate the feasibility of an investigational lead to be temporarily applied to and removed from the splenic neurovascular bunble (NVB)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON49161

Source
ToetsingOnline

Brief title
Splenic Nerve Stimulation During Esophagectomy

Condition

- Gastrointestinal therapeutic procedures

Synonym
Esophagectomy, oesophageal surgery

Research involving
Human

Sponsors and support

Primary sponsor: Galvani Bioelectronics
Source(s) of monetary or material Support: Galvani Bioelectronics;Stevenage;UK

Intervention

Keyword: Esophagetomy, Inflammation, Splenic nerve, Stimulation

Outcome measures

Primary outcome

Evaluate the feasibility of an investigational lead to be temporarily applied

to and removed from the NVB.

Evaluate the safety of placement, stimulation and removal of the lead around

the NVB.

Secondary outcome

Assess the impact of stimulation of the NVB on splenic blood flow.

Assess the impact of stimulation of the NVB on cardiovascular parameters.

Evaluate the impact of placement, stimulation, and removal of the lead around

the NVB on the postoperative inflammatory response.

Study description

Background summary

The current study is designed to evaluate the feasibility and safety of placing, stimulating, and removing a lead with cuff electrode (lead) on the splenic neurovascular bundle (NVB) during thoracolaparoscopic esophagectomy. Electrostimulation of the NVB may affect the inflammatory response to esophagectomy, though the ability to apply and remove a lead cuff, and to activate splenic nerves, has not been demonstrated in human studies. During minimally invasive esophagectomy, the splenic NVB is exposed as part of the lymph node dissection and is therefore easily accessible, thus creating an opportunity to test electrostimulation of the splenic NVB with minimal additional risk to the participants. In the first 3-5 patients the techniques will be optimized, therefore, their might be a change that they benefit less from the treatment compared to the next 10 patients in the study.

Study objective

Evaluate the feasibility of an investigational lead to be temporarily applied to and removed from the splenic neurovascular bunble (NVB)

Study design

A pliot safety study. At the point in the standard esophagectomy when the lymphadenectomy is performed, the splenic NVB is being isolated and an investigational lead will be implanted laparoscopically around the NVB and connected to an external pulse generator. An ultrasound transducer will be introduced to the abdomen and placed on the NVB to visualize splenic arterial blood flow during stimulation. The NVB will be stimulated three times (with intervening pauses to observe post-stimulation recovery from physiological changes) using parameters selected to cause a change in splenic arterial blood flow (a biomarker of NVB activation). Stimulation parameters may be adjusted over the course of the study based on experience with prior study participants. Blood samples will be taken before, and at certain pre-defined time points after, stimulation and recovery. The lead and ultrasound transducer will be removed after completion of stimulation, and the surgery will continue. Surgeon experience applying and removing the cuff electrode will be documented, in addition to the responses to NVB stimulation. Post-operative safety will be followed through 7-days post-surgery (or day of discharge if earlier).

Intervention

Placement of a lead with a cuff electrode on the splenic NVB and stimulation of these bundles

Study burden and risks

The risk of bleeding because the splenic artery is damaged is very small (<5%). It is possible that local sympathetic nerves going to the spleen can be damaged while placing or removing the instrument. However to date we do not have evidence that there are any clinical consequences related to this damage. There is a risk of damaging the pancreas, however this is risk is also present during a 'normal' esophagectomy (<5%).
Temporarily induced hemodynamic changes that are triggered by stimulation are constantly monitored by an anesthesiogist, who can use pharmacological agents if necessary.

There is limited burden for participants. The screening visit will take 15-30 minutes, but will be done following a regular outpatient clinic visit. All interventions take place during the esophagectomy and only one blood draw is performed when the patient is conscious.

Contacts

Public

Galvani Bioelectronics

Gunnels Wood Road 2
Stevenage SG1 2NY
GB
Scientific
Galvani Bioelectronics

Gunnels Wood Road 2
Stevenage SG1 2NY
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Female of non-reproductive potential or male
* Undergoing minimally invasive esophagectomy
* Confirmed presence of splenic NVB loop via imaging prior to surgery
* Age equal or above 21 years at the screening visit
* Capable of giving signed informed consent (IC)
* Normal blood pressure, or hypertensive managed with medication such that they are deemed fit for surgery

Exclusion criteria

* Previous splenectomy
* Existing implantable device
* Active pancreatitis or history of severe pancreatitis with complications, hepatic or splenic disease
* Use of oral steroids 4 weeks prior to inclusion

* Current use immunosuppressive agents or biologicals. Previous use of biologicals is allowed, if a washout period of 2 months is applied
* Use of anticoagulants within 1 week of surgery

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2019
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Lead with cuff electrode
Registration:	No

Ethics review

Approved WMO

Date:	12-09-2019
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	NL70757.100.19