Feasibility of Pre-emptive VACStent Placement after Ivor Lewis Esophagectomy, to Prevent Anastomotic Leakage (PREVENT feasibility study)

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We aim to evaluate the technical and logistic feasibility and safety of pre-emptive VACStent placement in patients undergoing esophagectomy with gastric conduit reconstruction, to prevent anastomotic leakage by early endoscopic vacuum therapy (EVT...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal ulceration and perforation
Study type	Interventional

Summary

ID

NL-OMON57220

Source
ToetsingOnline

Brief title
PREVENT feasibility study

Condition

- Gastrointestinal ulceration and perforation
- Gastrointestinal therapeutic procedures

Synonym
Esophageal anastomotic leakage, leakage in the esophagus

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Möller Medical GmbH (onder voorbehoud)

Intervention

Keyword: Anastomotic leakage, Endoscopic vacuum therapy, Esophagus, VACStent

Outcome measures

Primary outcome

Evaluate the technical and logistic feasibility and safety of pre-emptive

VACStent placement in patients undergoing esophagectomy with gastric conduit

reconstruction and intrathoracic anastomosis to prevent anastomotic leakage

Secondary outcome

- To study the rate of anastomotic leakage

- To study the quality of life/quality of recovery

- To study the length of ICU- and in-hospital stay

- To study the 30-day morbidity and mortality

Study description

Background summary

Anastomotic leakage is a severe complication after esophagectomy, associated with increased mortality, morbidity, and prolonged ICU- and in-hospital stay.[1, 2] The incidence of anastomotic leakage of an intrathoracic anastomosis ranges from 6 to 41%.[3] Patient-related prognostic factors for development of anastomotic leakage include male gender, ASA score > III and several comorbidities (e.g. diabetes mellitus, pulmonary and vascular comorbidity).[4] At our hospital, endoscopic vacuum therapy (EVT) using a polyurethane sponge (EsoSPONGE*; Braun B. Melsungen, Germany) was introduced as primary treatment of anastomotic leakage after esophagectomy in 2018. EVT has shown great efficacy and safety in patients with anastomotic leakage after upper gastro-intestinal surgery, with success rates from 80 to 100% and adverse

event rates from 0 to 10% [5-8]. A recent development in the field of EVT is the VACStent (MICRO-TECH Europe GmbH, Du*sseldorf, Germany): a fully covered stent with a polyurethane sponge on its outer surface. The VACStent combines the sealing effect of a stent with advantages of negative pressure wound therapy, while the vacuum prevents dislocation of the stent. Furthermore, contrary to the sponge that blocks the esophageal lumen, with the VACStent the esophageal lumen remains open, allowing for oral intake. Literature on the VACStent is scarce, but shows that this device is a feasible and effective treatment for patients with post-surgical leakages, with successful and safe application of EVT in 100% and a leakage closure rate of 80-100% [9, 10]. According to the adagium *prevention is better than cure*, we aim to reduce the rate of anastomotic leakage after esophagectomy, to possibly prevent the associated increased mortality, morbidity, and prolonged ICU- and in-hospital stay. Placement of pre-emptive EVT directly following Ivor Lewis esophagectomy could possibly reduce the risk of anastomotic leakage.[11] With a pre-emptive VACStent, intake remains possible and the Enhanced Recovery After Surgery (ERAS) protocol can be maintained. This clinical feasibility study is the first to translate the use of the novel VACStent-device from *treatment* to *prevention* of anastomotic leakage. It will combine the opportunities of our unique large surgical volume, our extensive experience with EVT, and the novel VACStent-device, which combines the advantages of EVT and covered stents. Based on the results of this feasibility study, we will be able to design a randomized controlled trial comparing rate of anastomotic leakage in patients undergoing Ivor Lewis esophagectomy with gastric conduit reconstruction with or without pre-emptive VACStent placement. References: 1. Fabbi M, Hagens ERC, van Berge Henegouwen MI et al. Anastomotic leakage after esophagectomy for esophageal cancer: definitions, diagnostics, and treatment. Dis Esophagus 2021; 34. doi:10.1093/dote/doaa039 2. Alanezi K, Urschel JD. Mortality secondary to esophageal anastomotic leak. Ann Thorac Cardiovasc Surg 2004; 10: 71-75 3. Gooszen JAH, Goense L, Gisbertz SS et al. Intrathoracic versus cervical anastomosis and predictors of anastomotic leakage after oesophagectomy for cancer. Br J Surg 2018; 105: 552-560. doi:10.1002/bjs.10728 4. van Kooten RT, Voeten DM, Steyerberg EW et al. Patient-Related Prognostic Factors for Anastomotic Leakage, Major Complications, and Short-Term Mortality Following Esophagectomy for Cancer: A Systematic Review and Meta-Analyses. Ann Surg Oncol 2022; 29: 1358-1373. doi:10.1245/s10434-021-10734-3 5. Aziz M, Haghbin H, Sharma S et al. Safety and effectiveness of endoluminal vacuum-assisted closure for esophageal defects: Systematic review and meta-analysis. Endosc Int Open 2021; 9: E1371-E1380. doi:10.1055/a-1508-5947 6. Tavares G, Tustumi F, Tristao LS et al. Endoscopic vacuum therapy for anastomotic leak in esophagectomy and total gastrectomy: a systematic review and meta-analysis. Dis Esophagus 2021; 34: 1-10. doi:10.1093/dote/doaa132 7. Scognamiglio P, Reeh M, Karstens K et al. Endoscopic vacuum therapy versus stenting for postoperative esophago-enteric anastomotic leakage: systematic review and meta-analysis. Endoscopy 2020; 52: 632-642. doi:10.1055/a-1149-1741 8. do Monte Junior ES, de Moura DTH, Ribeiro IB et al. Endoscopic vacuum therapy versus endoscopic stenting for upper gastrointestinal transmural defects: Systematic review and meta-analysis. Dig

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Study objective

We aim to evaluate the technical and logistic feasibility and safety of pre-emptive VACStent placement in patients undergoing esophagectomy with gastric conduit reconstruction, to prevent anastomotic leakage by early endoscopic vacuum therapy (EVT). Outcomes of this study can then be used for determination of a formal sample size required to design a larger clinical trial: a randomized controlled trial of pre-emptive use of VACStent placement after esophagectomy.

Study design

This is an investigator initiated, single-center, prospective, feasibility study of pre-emptive VACStent placement after Ivor Lewis esophagectomy to reduce the risk of anastomotic leakage.

Intervention

Endoscopic placement of a pre-emptive VACStent, right after Ivor Lewis esophagectomy in the operation room, and removal after 5-7 days.

Study burden and risks

Anastomotic leakage is a severe complication with an incidence up to 30%. This complication is associated with severe morbidity, including prolonged (ICU-and) hospital stay, multiple endoscopies or even re-operations, with possibly a resection of the esophagus and therefore loss of continuity of the gastro-intestinal tract. We expect the VACStent to reduce the risk of anastomotic leakage in this patient group. Reduction of this risk would therefore have great benefits. Treatment, diagnostics and follow-up will not differ from the standard treatment protocol for the included patients. A VACStent will be placed immediately after surgery during the same procedure and 5-7 days later an additional endoscopy will be performed. During this endoscopy, the VACStent will be removed and the anastomosis will be evaluated. An additional benefit is that any potential post-operative problems irregularities regarding the anastomosis will be discovered earlier on. Apart from the described additional interventions for placement and removal of the VACStent, the standard treatment protocol will be followed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Undergoing an esophagectomy with gastric conduit reconstruction and intrathoracic anastomosis (Ivor Lewis) at the Amsterdam UMC

Exclusion criteria

Patients with contra-indications for endoscopic vacuum therapy: defect length larger than 5 cm, defect less than 2cm from the proximal esophageal sphincter and ileus. Patients unable to sign informed consent.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2024
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	VACStent
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	18-03-2024
Application type:	First submission
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
CCMO	NL83726.018.23