Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	ClinicalTrials.gov
Last refreshed on:	6 April 2020
Main ID:	NCT03962244
Date of registration:	21/05/2019
Prospective Registration:	Yes
Primary sponsor:	University Hospital of Cologne
Public title:	Stent Therapy Versus Endoscopic Vacuum Therapy for Anastomotic Leaks After Esophagectomy EsoLeak
Scientific title:	Endoscopic Management of ESOphago-gastric Anastomotic LEAKages (EsoLeak): Stent Therapy Versus Endoscopic Vacuum Therapy
Date of first enrolment:	April 1, 2020
Target sample size:	40
Recruitment status:	Not yet recruiting
URL:	https://clinicaltrials.gov/show/NCT03962244
Study type:	Observational
Study design:	
Phase:	

Countries of recruitment

Germany

Contacts

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Key inclusion & exclusion criteria

Inclusion Criteria:

- Histologically confirmed oesophageal carcinoma or similarly operated neoplasia (e.g., GIST, NET, subepithelial tumors)

- Esophagectomy with an intrathoracic esophago-gastric anastomosis

- Radiologically or endoscopically diagnosed esophago-gastric anastomotic leakage

- Clinical symptoms / symptoms due to insufficiency or increase in signs of inflammation, most likely as a result of anastomotic leakage

- Age =18 years

- To empower the patient to understand the scope of the study and its consequences or

information, to consent to it and to sign the educational documents.

- Written declaration of consent of the patient to be included. If the patient is unable to sign by hand, a witness must confirm the oral examination by signature.

Exclusion Criteria:

- Macroscopically incompletely resected tumor (R2), palliative resection

- Endoscopically verified necrosis or critical ischemia of the anastomotic region of the interponate

- Size of insufficiency more than 50% of circumference

- Impossibility of radiological interventional insertion of a drainage

- Early anastomotic leak (= 48 hours postoperatively), late insufficiencies (> 4 weeks)

- Therapeutic anticoagulation

- Severe septic shock that indicates surgical therapy

- Pregnant and lactating women

Age minimum: 18 Years
Age maximum: N/A
Gender: All

Health Condition(s) or Problem(s) studied

Leaks, Anastomotic

Intervention(s)

Device: EsoSponge

Device: Self-Expanding Metal Stent

Primary Outcome(s)

Satisfaction of treatment assessed by EORTC QLQ - OES18 [Time Frame: 6 months]

Secondary Outcome(s)

Secondary ID(s)

19-1201

Source(s) of Monetary Support

Please refer to primary and secondary sponsors

Secondary Sponsor(s)

Universitätsklinikum Hamburg-Eppendorf

Ethics review

Results

Results available:
Date Posted:
Date Completed:
URL:

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