



Trial Description

Title

Is the blood flow of terminal ileum after esophagectomy sufficient for oesophageal anastomosis?

Trial Acronym

[---]*

URL of the trial

<https://archiv.ub.uni-marburg.de/diss/z2018/0421/>

Brief Summary in Lay Language

Aim of the study is to examine the blood supply to the terminal ileum (last part of the small intestine) after deduction of A. iliocolica (and possibly colic artery) and obtaining the middle colic artery. In some cases, the right hemicolon (first part of the colon) is used to restore continuity of the esophagus. We will check the blood flow to the terminal ileum to prove whether the terminal ileum is to use together with the re hemicolon for continuity restoration. - After removal of the lower esophageal third and removal of the stomach. The preparation steps in reconstruction of the esophagus and at an open right hemicolectomy are the same. Therefore, the measurement of blood flow to the terminal ileum is at an open right hemicolectomy the ideal preparation model.

Brief Summary in Scientific Language

Am Klinikum Minden right hemicolon was used to obtain the terminal ileum as Esophageal replacement in 3 patients. In preparation of the graft were first the artery and vein ileocolica and colic artery sold centrally. Here noticed in every case that the terminal ileum having a full perfusion. After transection of the ileum arterial blood supply to the intestinal wall of the ileum was each detectable, although perfusion "only" on the middle colic artery was present. Then we decided to get into any of the three cases, the perfused ileum and Ileocaekalklappe and establish proximal anastomosis after esophagectomy between Ösophagusstumpf and the terminal ileum.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

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Organizational Data



- DRKS-ID: **DRKS00008934**
- Date of Registration in DRKS: **2015/10/09**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2014-671-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

Health condition or Problem studied

- ICD10: **C15.5 - Malignant neoplasm: Lower third of oesophagus**
- ICD10: **C16.0 - Malignant neoplasm: Cardia**

Interventions/Observational Groups

- Arm 1: **All patients to whom an open right hemicolectomy is indicated. In the study, the circulation of the terminal ileum is checked (last part of the small intestine) - after deduction of A. and V. iliocolica and right colic artery and keeping the A. media colic. If the circulation of this part is sufficient, this part (terminal ileum) can theoretically be used as a reconstructions' part at another surgery (oesophageal reconstruction after oesophageal resection and after stomach resection) . Since the preparation steps between the two operations are almost similar (until the point of dismissal of the right colic artery), the open right hemicolectomy is the perfect preparation patterns.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**



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Primary Outcome

Using the fluorescence measurement with VITOM (R) Device of the company Karl Storz, we will measure the perfusion in 20 patients in whom an oncology hemicolectomy is required due to colon cancer or a suspected colon cancer right after full mobilization of the right hemicolon and central ligature of the artery and vein ileocolica and transversum in the presence also of the right colic artery and severing of the terminal ileum and the associated small intestine mesentery and transection of the intestine tube of the colon prior to severing of the colon mesentery a perfusion of the small intestine ends and colon ends on each of the two sides of the severed bowel made. The tumor-bearing part of bowel that will be resected is defined hereinafter in this study as a "model graft". Since we in principle renounce setting bowel terminals in the intestinal surgery, as not to affect the intestinal wall structure to anastomosing intestines, no change in the routine operation to answer the study question is necessary at this point. The intraoperative and perioperative course of patients is documented. The perfusion of small intestine in the time of measurement on both sides after transection and anastomosis heals whether the downright after resection will be documented. To reduce the influence factors of each trial operations of a maximum of two different responsible operators (notified operators of the cancer center: BG, JL) will be assisted or even performed.

Carried out to assess the sufficiency of an intestinal anastomosis blood flow to the bowel ends of the "Model transplant" and the respective corresponding remaining intestine ends

- a perfusion with VITOM (R) Device of the company Karl Storz,**
- an assessment by the responsible surgeon immediately before perfusion intraoperatively,**
- an assessment by a non-participating in Operation Specialist for visceral surgery immediately before perfusion intraoperatively**
- an assessment of immediately before perfusion intraoperatively custom built images by two other independent non-participating in the operation Specialists in visceral surgery.**

Documenting the anastomotic healing after resection of "transplant model" followed by anastomosis of the two remaining corresponding intestine ends in the postoperative course is and correlated with the aforementioned assessments.

To practice the course of the study operations, a pilot study is planned with 5 patients. With a total of 20 expected oncological hemicolectomies right is to be expected with a time of ½ to 1 year for the study included the pilot study.

During the operation, the terminal ileum is cut (last part of small intestine) with stapler. Thereafter, the artery and vein iliocolica and artery and vein artery dexter (if available) are cut and the middle colic artery will be kept. At this time, the approved drug ICG-Pulsion is injected in the patients and with a special camera from the company Karl Storz the microcirculation will be observed macroscopically (images with fluorescence, no numbers, so if much fluorescence effect then the perfusion is good, if little or no fluorescence effect, then the perfusion is bad). The result is documented (photos, recordings). It is a routine procedure in operations where an anastomosis will be performed. After completion of the observation of the perfusion, the question ends with the patient (end point). The following questions are from the surgeon and an experienced visceral surgeons intraoperatively (doctor is available) and postoperatively to answer (the images - fluorescence effect - are described by another colleague, for example, good blood circulation, poor circulation, etc.)

A) main question

1. How often the two ends of the "Model transplant" for an intestinal anastomosis are sufficiently supplied with blood?

In this study, the perfusion of the terminal ileum is (last part of the small intestine) measured in patients where an open right hemikolektomy been indexed. If blood flow/perfusion is sufficient, the terminal ileum could be used as anastomosis for continuity restoration at another surgery (oesophageal reconstruction after resection of oesophagus and stomach) because the steps up to the point of dismissal of the right colic artery and vein are same.

Secondary Outcome

B) In addition to questions

2. How often does the perfusion of small intestine side of the "Model transplant" is worse than that of the later anastomosed small intestine in the fluorescence method?

3. the perfusion of the colon side of the "Model transplant" How often is worse than that of the later anastomosed colon in fluorescence method?

4. How often does the perfusion of small intestine side of the "Model transplant" is worse than that of the later anastomosed small intestine in the judgment of the responsible surgeon?

5. How often is the perfusion of the colon side of the "Model transplant" worse than that of the later anastomosed colon in the judgment of the responsible surgeon?

6. How often is the perfusion of small intestine side of the "Model transplant" worse than that of the later anastomosed small intestine in the judgment of the independent visceral surgeons?

7. How often is the perfusion of the colon side of the "Model transplant" worse than that of the later anastomosed colon in the judgment of the independent visceral surgeons?

8. How often is the perfusion of small intestine side of the "Model graft" worse than the later anastomosed small intestine in the assessment on the basis of intraoperative photographic documentation by two independent visceral surgeons?

9. How often is the perfusion of the colon side of the "Model transplant" worse than that of the later anastomosed colon based intraoperative photographic documentation by two independent visceral surgeons?

10. How often heals the anastomosis downright among patients in whom the perfusion of each corresponding intestinal ends with reference to the fluorescence method, was evaluated intraoperatively by the surgeon and the independent visceral surgeons and by the independent visceral surgeons on the basis of photographic documentation.



Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Allgemeinchirurgie, JWK Klinikum Minden**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/20**
- Target Sample Size: **25**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients to whom an open right hemicolectomy has been indexed. Since the pattern preparation and preparation steps are the same in an open right hemicolectomy and esophagus reconstruction, the measurements are performed in patients in which an open right hemicolectomy has been indexed. (Preparation steps up to the point of deposition of the right colic artery the same for both operations).

Exclusion criteria

- age <18 years of age and not emancipated patients**
- **colon resection, in which a resection is indexed taking along the middle colic artery (eg hepatic flexure carcinoma)**
 - **Headed colon resection and operations in which the receipt of the perfusion of the middle colic artery and the right-hand edge of arcades is questionable.**
 - **"broken" colon cancer, that is, advanced T3 and T4 carcinoma according to WHO and advanced regional lymph node metastases.**
 - **unavailability of the designated for this study responsible surgeon.**
 - **Known and expected severe intra-abdominal adhesions eg to large intra-abdominal surgery or after severe peritonitis.**
 - **Synchronous operations required that have a potential impact on the intestinal**

circulation

- **BMI > 35**
- **Severe systemic diseases that are expected to impaired tissue perfusion and anastomotic healing such as decompensated right heart failure, high-dose immunosuppression etc.**
- **Patient is not willing to participate in the study**
- **Pregnant**

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/05/09**

Trial Publications, Results and other documents

- Background literature **Köckerling F, Rose J, schneider c et al. (1999), Laparoscopic colorectal anastomosis: risk of postoperative leakage. Results of a multicenter study. Laparoscopic Colorectal Surgery Study**
- Background literature **Willis S, Stumpf M (2004), Insuffizienzen nach Eingriffen am unteren Gastrointestinaltrakt.**
- Background literature **Carus T. et al:, Laparoscopic fluorescence angiography with indocyanine green to control the**
- Background literature **MOTOYAMA ET AL. USE OF COLON BY POSTERIOR MEDIASTINAL ROUTE. Ann Thorac Surg 2007;83:1273-8**
- Paper **Promotion online**

* This entry means the parameter is not applicable or has not been set.

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