Trial Description

Title

Surgery for adenocarcinoma of the gastroesophageal junction (GEJ) type II: Transthoracic esophagectomy vs. transhiatal extended gastrectomy.

Trial Acronym

CARDIA Trial

URL of the trial

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Brief Summary in Lay Language

The CARDIA study examines malignant tumors located directly at the transition between the esophagus and stomach. By surgically removing the tumour, this cancer can be cured in some of the affected patients. There are currently two possible surgical procedures.
One procedure is the transthoracic oesophagectomy with stomach elevation. During this procedure, a large part of the oesophagus is removed together with the oesophageal-gastric-transition. The stomach is then formed into a tube and connected to the rest of the esophagus in the chest cavity.
The other operation is the transhiatal extended gastrectomy. In this procedure, the stomach is removed together with the oesophageal-gastric-transition. A connection is then created between the esophagus and a part of the small intestine.
Both procedures allow complete removal of the tumor. However, they are associated with different risks and complications. So far, it has not been possible to determine scientifically which of the two operations is better suited for the treatment of transitional tumors. The aim of this clinical study is therefore to compare the two procedures in terms of healing rates and the resulting quality of life.

Brief Summary in Scientific Language

Adenocarcinomas of the gastroesophageal Junction (GEJ) type II can be resected either by transthoracic oesophageectomy or transhiatal extended gastrectomy. Both surgical procedures allow a complete tumor resection. To date, it has not been determined which surgery is superior in terms of quality of life, oncological outcome and survival, as only retrospective studies with contradictory results have been conducted so far. The CARDIA trial compares both surgical procedures in a non-blinded, multinational, multicenter, prospectively randomized study design. Patients with an GEJ type II tumor that can be resected by both transthoracic esophagectomy and transhiatal gastrectomy will be enrolled in the trial and will be operated after randomization using one of the investigated surgical procedure. Primary endpoint is overall survival. Secondary endpoints are complete resection (R0), number and location of tumor-infiltrated lymph nodes, postoperative complications, disease-free survival, quality of life and cost-effectiveness. Postoperative survival, disease-free survival and quality of life are monitored for 24 months after discharge. Overall survival is then monitored

through quarterly telephone calls up to 60 months after surgery.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00016923**
- Date of Registration in DRKS: **2019/08/02**
- 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.: **19-1376 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **C16.0 - Malignant neoplasm: Cardia**

Interventions/Observational Groups

- Arm 1: **Transthoracic esophagectomy (removal of the esophagus and intrathoracic connection of the esophagus to the stomach)**
- Arm 2: **Transhiatal extended gastrectomy (Removal of the stomach and the lower part of the esophagus with esophageal jejunostomy)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Overall survival (Follow-up up to 60 months after discharge)

Secondary Outcome

Complete (R0) resection, post-operative complications according to the Dindo-Clavien classification, number and Tumor Infiltration of lymph nodes at dissection, quality of life (EORTC QLQ-C30, -STO22, -OG25 after 3, 6, 12, 18, 24 months), cost-effectiveness

Countries of recruitment

- DE **Germany**
- NL **Netherlands**

Locations of Recruitment

- University Medical Center **Universitätsklinik Köln, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/04/16**
- Target Sample Size: **262**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

• Histologically proven adenocarcinoma of the GEJ type II
• Non-metastatic tumor, resectable by both transthoracic esophagectomy and transhiatal extended gastrectomy according to the local surgical investigator
• Age ≥ 18
• ECOG Eastern Cooperative Oncology Group (ECOG) performance status 0–2
• ASA < 4.
• Pre-treatment stage cT1-4a N0/N+, M0
• In case of stage cT4a, curative resectability must be explicitly verified by the local surgical investigator prior to randomization
• Patients with locally advanced tumors (T3-T4 or N+) who received four cycles of chemotherapy (FLOT) preoperatively
• Negative serum pregnancy test during screening period for women of child-bearing age
• Patients with a cardiac history should receive a cardiology consultation and should have a left ventricular ejection fraction > 50% (determined by echocardiography)
• Adequate respiratory function (pulmonary function tests only necessary in symptomatic patients) with FEV1>/= 1.5 l/s
• Adequate bone marrow function (white blood cells > 3x10^9 /l; hemoglobin > 9 g/dl; platelets > 100x10^9 /l), renal function (glomerular filtration rate >60 ml/min), and liver function (total bilirubin < 1.5x upper level of normal (ULN), aspartate transaminase (AST) < 2.5x ULN and alanine transaminase (ALT) < 3x ULN)
• Written informed consent

Exclusion criteria

• Tumors of squamous, adenosquamous or another non-adenocarcinoma histology
• Advanced inoperable or metastatic GEJ type II adenocarcinoma
• GEJ type II adenocarcinoma staged cT4b, M+
• GEJ type II cT4a evaluated as not curatively resectable by the local surgical investigator
• Histologically proven adenocarcinoma of the GEJ type I and III
• Severe tumor stenosis preventing endoscopic tumor classification
• Tumor expanding more than 5 cm proximal of the GEJ
• Tumor resectable only by transthoracic esophagectomy or only by transhiatal extended gastrectomy, according to the local surgical investigator
• Positive lymph nodes only resectable by transthoracic esophagectomy (i.e. in the mid-upper mediastinum) or only resectable by transhiatal extended gastrectomy according to the local surgical investigator.
• Patients with locally advanced tumors (T3-T4 or N+) who did not receive chemotherapy (FLOT) preoperatively or received more or less than the allowed 4 cycles of chemotherapy
• Clinically significant (active) cardiac disease (e.g. symptomatic coronary artery disease or myocardial infarction within last 12 months)

• Clinically significant lung disease (forced expiratory volume in one second (FEV1) < 1.5 l/s)
• Pregnant women and nursing mothers
• Persons with any kind of dependency on the principal investigator or employed by the sponsor or principal investigator
• Legally incapacitated persons
• Persons held in an institution by legal or official order

Addresses

■ **Primary Sponsor**

Universitätsklinik Köln Klinik und Poliklinik für Allgemein- Viszeral- und Tumorchirurgie
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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

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

**** This entry means that data is not displayed due to insufficient data privacy clearing.*