

SURGERY FOR ADENOCARCINOMA OF THE GASTROESOPHAGEAL JUNCTION (GEJ) TYPE II: TRANSTHORACIC ESOPHAGECTOMY VS. TRANSHIATAL EXTENDED GASTRECTOMY (CARDIA trial)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON52610

Source

ToetsingOnline

Brief title

CARDIA trial

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym

cancer of the junction between stomach and esophagus, siewert type 2 carcinoma, true cardia carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: University of Cologne, Germany

Source(s) of monetary or material Support: Bundesministerium für Bildung und Forschung (BMBF);Duitsland

Intervention

Keyword: Gastroesophageal junction cancer, Transhiatal extended gastrectomy, Transthoracic esophagectomy

Outcome measures

Primary outcome

The trial is powered to show superiority for esophagectomy with regards to the primary efficacy endpoint overall survival.

Secondary outcome

Secondary endpoints are complete resection (R0), number and localization of tumor infiltrated lymph nodes at dissection, post-operative complications, disease-free survival, quality of life and cost-effectiveness. Postoperative survival, disease-free survival and quality of life will be followed-up for 24 months after discharge. Further survival follow-up will be conducted as quarterly phone calls up to 60 months.

Study description

Background summary

Adenocarcinoma of the gastroesophageal junction (GEJ) Siewert type II can be resected by transthoracic esophagectomy or transhiatal extended gastrectomy. Both allow for a complete tumor resection, yet there is an ongoing controversy about which surgical approach is superior with regards to quality of life,

oncological outcomes and survival. While some studies suggest a better oncological outcome after transthoracic esophagectomy, others favor transhiatal extended gastrectomy for a better postoperative quality of life. To date, only retrospective studies are available, showing ambiguous results.

Study objective

The aim of the study is to compare transthoracic esophagectomy versus transhiatal extended gastrectomy in patients with GEJ type II tumors. It is hypothesized that esophagectomy allows for a higher rate of radical resections and a more complete mediastinal lymph node dissection, resulting in a longer overall survival, while still providing an acceptable quality of life and an acceptable cost-effectiveness.

Study design

This study is a non-blinded, multinational, multicenter, prospective, randomized controlled superiority trial.

Intervention

The participants are randomized to either transthoracic esophagectomy or transhiatal extended gastrectomy.

Study burden and risks

Both operations are procedures that are recommended in the Dutch guidelines (oncoline.nl) and the German S3 guidelines as standard therapy for the investigated tumor disease, there is neither an additional risk nor a direct benefit for the participating patients. We would classify the current study as neglectable risk. Compared to standard care, the additional burden for patients consists of filling in 8 quality of life questionnaires over the course of 2 years, each of which takes 15-30 minutes to complete.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Principal inclusion criteria:

- Histologically proven adenocarcinoma of the GEJ type II
- Non distant metastatic tumor resectable by both transthoracic esophagectomy and transhiatal extended gastrectomy
- Age ≥ 18
- ECOG performance status < 3
- ASA < 4
- Patients with locally advanced tumors (T3-T4 or N+) who received at least one cycle of chemotherapy (FLOT) preoperatively

Principal exclusion criteria:

- Adenocarcinoma of the GEJ type I and III
- Tumor resectable only by transthoracic esophagectomy or only by transhiatal extended gastrectomy
- Positive lymph nodes only resectable by transthoracic esophagectomy (i.e. in the mid-upper mediastinum) or only resectable by transhiatal extended gastrectomy

Exclusion criteria

- Adenocarcinoma of the GEJ type I and III
- Tumor resectable only by transthoracic esophagectomy or only by transhiatal extended gastrectomy

- Positive lymph nodes only resectable by transthoracic esophagectomy (i.e. in the mid-upper mediastinum) or only resectable by transhiatal extended gastrectomy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	06-12-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO	
Date:	27-05-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	16-06-2022
Application type:	Amendment
Review commission:	METC NedMec

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
Other	Deutsches Register Klinischer Studien. DRKS-number: 00016923
CCMO	NL73053.041.20