Intrathoracic versus Cervical ANastomosis after minimally invasive esophagectomy for esophageal cancer: a randomized controlled trial

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The ICAN research question is: What is the effectiveness of an intrathoracic compared to a cervical esophagogastric anastomosis after (hybrid) minimally invasive esophagectomy in terms of anastomotic leakage, morbidity, quality of life and costs?

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

Summary

ID

NL-OMON45081

Source
ToetsingOnline

Brief title
ICAN trial

Condition

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

Synonym
esophageal cancer, esophageal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cervical anastomosis, Esophageal carcinoma, Intrathoracic anastomosis, Minimally invasive esophagectomy

Outcome measures

Primary outcome

Anastomotic leakage requiring endoscopic, radiologic or surgical reintervention

Secondary outcome

Secondary outcome parameters (amongst others): quality of life, functional

morbidity, complications, organ failure, reintervention, length of stay,

mortality, and costs.

Study description

Background summary

Esophageal carcinoma is a complex disease process of increasing incidence that exerts a social and financial burden on global
healthcare systems. Particularly, anastomotic leakage is an important post-operative complication that results in major
morbidity, reoperation, delayed discharge, and psychological and financial distress. It has been suggested that anastomotic
leakage, major morbidity, and therefore associated costs are lower after an intrathoracic esophagogastric anastomosis as
compared to a cervical esophagogastric anastomosis. However, high quality evidence is lacking.

Study objective

The ICAN research question is: What is the effectiveness of an intrathoracic compared to a cervical esophagogastric
anastomosis after (hybrid) minimally invasive esophagectomy in terms of

anastomotic leakage, morbidity, quality of life and costs?

Study design

Open multicentre randomized controlled superiority trial

Intervention

(Hybrid) minimally invasive esophagectomy with an intrathoracic esophagogastric anastomosis (intervention group) is compared to (hybrid) minimally invasive esophagectomy with cervical esophagogastric anastomosis (control group)

Study burden and risks

One extra telefphone call or study visit preoperatively is required if the surgeon decides to approach the patient after neoadjuvant therapy. All other visits (5-9 weeks after surgery, 12-16 weeks after surgery, 22-30 weeks after surgery, 48-56 weeks after surgery and 100-108 weeks after surgery) coincide with normal postoperative follow-up visits and do not contribute to the participant burden. QOL questionnaires (EuroQol 5D, EORTC- QLQ C30 and EORTC-QLQ OG25) are filled in 6 times per patient (15 minutes to complete). The Medical Consumption Questionnaire (MCQ) and Productivity Cost Questionnaire (PCQ) are filled in 5 times per patient (25 minutes to complete). Other follow-up or diagnostic procedures do not differ from regular practice.

Both a CA and ITA are currently accepted surgical techniques for reconstructing continuity of the gastrointestinal tract after esophagectomy without convincing evidence to prefer one technique over the other. Therefore, no additional risks are associated with participation.

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

- Age >=18 years.
- Histologically proven esophageal carcinoma below the carina or at the level of the gastro-esophageal junction (Siewert 2).
- Resectable tumour (T1b-4a N0-3 M0).
- Mental, physical and geographical ability to undergo treatment and follow-up.
- Ability to provide written informed consent.

Exclusion criteria

- Previous major gastric or major thoracic surgery rendering (hybrid) minimally invasive esophagectomy unfeasible).
- Secondary, prognosis determining malignancy.

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:	Recruitment stopped
Start date (anticipated):	08-06-2016
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	02-10-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-10-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-04-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-05-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-09-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-05-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	11-08-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-03-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL46843.091.14