

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

Published: 02-10-2014

Last updated: 18-07-2024

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?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Malignant and unspecified neoplasms gastrointestinal NEC
<b>Study type</b>	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 telephone 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**

### **Public**

Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10  
Nijmegen 6525GA  
NL

### **Scientific**

Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10  
Nijmegen 6525GA  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Age  $\geq 18$  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