

Traditional invasive vs. minimally invasive esophagectomy

Published: 24-04-2009

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Optimalisation of the surgical treatment of esophageal cancer.

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

Summary

ID

NL-OMON33887

Source

ToetsingOnline

Brief title

TIME-trial

Condition

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

Synonym

Oesophageal cancer

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: carcinoma, esophagectomy, minimally invasive, traditional

Outcome measures

Primary outcome

Pulmonary complications.

Secondary outcome

General morbidity, mortality, operation related events (operation time, per-operative complications), pain, length of ICU-MCU stay, length of hospital stay, return to normal diet, quality of life, costs, pathologic examination of the specimen.

Study description

Background summary

Surgery for cancer of the esophagus is considered to be one of the most extensive and traumatic oncological surgical procedures. Open resection not only involves a long operation time and large incisions but also necessitates postoperative care in the intensive care unit, a long in-hospital recovery and carries a significant risk of morbidity and death. Minimally invasive esophagectomy can reduce the extensive nature of the required surgery and the associated risk of morbidity and mortality. Furthermore, reduction of the postoperative morbidity shortens recovery time. Evidence of the short term benefits of minimally invasive surgery over open procedures is accumulating. Faster postoperative recovery, less perioperative complications and a shorter duration of hospital stay appear to be the main advantages. However, no prospective trial has been conducted to date. Therefore, the following trial is proposed for the purpose of improving the efficacy of surgery for esophageal cancer.

Study objective

Optimalisation of the surgical treatment of esophageal cancer.

Study design

Randomized controlled trial.

Intervention

Traditional three stage (thoracotomy, laparotomy, cervicotomy) esophageal resection versus minimally invasive three stage (thoracoscopy, laparoscopy, cervicotomy) transthoracic esophageal resection in prone position in patients with resectable esophageal cancer.

Study burden and risks

To date the beneficiary effects of minimally invasive resections are reported in case-series. No randomized trial has been performed comparing minimally invasive resection with open resection. De results of these case-series do not show extra risks involving minimally invasive esophageal resection. Based on current literature, no extra risks are foreseen in this first randomized trial. Furthermore, during evaluations at the outpatient clinic at 6 weeks, 6 months and 1 year after surgery patients are requested to complete 2 health related questionnaires.

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

1. Histologically proven squamous cell carcinoma, adenocarcinoma or undifferentiated carcinoma of the intrathoracic esophagus.
2. Surgical resectable (T1-3, N0-1, M0).
3. Age * 18 and * 75 years.
4. European Clinical Oncology Group (ECOG) performance status 0,1 or 2.
5. Written, informed consent.

Exclusion criteria

1. Cervical and gastro-esophageal junction carcinoma.
2. Prior thoracic surgery.
3. No informed consent

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): 25-05-2009
Enrollment: 0
Type: Actual

Ethics review

Approved WMO
Date: 24-04-2009
Application type: First submission
Review commission: METC Amsterdam UMC
Approved WMO
Date: 31-03-2010
Application type: Amendment
Review commission: METC Amsterdam UMC

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	NL25587.029.09