Traditional invasive versus minimally invasive esophagectomy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20420

Source
NTR

Brief title
TIME-trial

Health condition

oesophagectomy, minimally invasive, open, cancer

Sponsors and support

Primary sponsor: VU university medical center
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Respiratory complications (infections) within two weeks after the operation.

Secondary outcome

1. Operation related events (e.g. duration of operation, blood-loss);

2. Re-operations;

3. General morbidity (major and minor);

4. Length of ICU and hospital stay (days);

5. Type and number of analgesics needed after operation;

6. VAS-pain-score;

7. Return to fluid and normal diet;

8. Quality of life questionnaires (SF-36 and EORTC QLQ-OES18);

9. Quality of the specimen resected (e.g. length of specimen, number and location of lymph nodes resected and circumferential resection margin);

10. Hospital mortality;

11. Readmissions;

12. Survival.

Study description

Background summary

Background:

There is a rise in incidence of oesophageal carcinoma due to increasing incidence of adenocarcinoma. Probably the only curative option to date is the use of neoadjuvant therapy followed by surgical resection. Traditional open oesophageal resection is associated with a high morbidity and mortality rate. Furthermore, this approach involves long intensive care unit stay, in-hospital stay and long recovery period. Minimally invasive oesophagectomy could reduce the morbidity and accelerate the postoperative recovery.

Methods/Design:

Comparison between traditional open and minimally invasive oesphagectomy in a multi-centered, randomized trial. Patients with a resectable intrathoracic oesophageal carcinoma, including the gastro-oesophageal junction tumors (Siewert I) are eligible for inclusion. Prior thoracic surgery and cervical oesophageal carcinoma are indications for exclusion. The

surgical technique involves a right thoracotomy with lung blockade and laparotomy either with a cervical or thoracic anastomosis for the traditional group. The minimally invasive procedure involves a right thoracoscopy in prone position with a single lumen tube and laparoscopy either with a cervical or thoracic anastomosis. All patients in both groups will undergo identical pre-operative and post-operative protocol. Primary endpoint of this study are postoperative respiratory complications within the first two postoperative weeks confirmed by clinical, radiological and sputum culture data. Secondary endpoints are the operative data, the postoperative data and oncological data such as quality of the specimen and survival. Operative data include duration of the operation, blood loss and conversion to open procedure. Postoperative data include morbidity (major and minor), quality of life tests and hospital stay.
Based on current literature and the experience of all participating centers, an incidence of pulmonary complications for 57% in the traditional arm and 29% in the minimally invasive arm, it is estimated that per arm 48 patients are needed. This is based on a two-sided significance level (alpha) of 0.05 and a power of 0.80. Knowing that approximately 20% of the patients will be excluded, we will randomize 60 patients per arm.

Discussion:

The TIME-trial is a prospective, multi-center, randomized study to define the role of minimally invasive oesophageal resection in patients with resectable intrathoracic and junction oesophageal cancer.

Study objective

Patients undergoing a minimally invasive oesophagectomy have fewer morbidity, a shorter duration of the intensive care unit (ICU) admission and a better quality of life than following the traditional approach.

Study design

1. Before neo-adjuvant therapy;

2. After neo-adjuvant therapy (before surgery);

3. Post-operative in hospital period;

4. 6 weeks after surgery;

5. 3 months after surgery;

6. 6 months after surgery;

7. 1 year after surgery.

Intervention

Comparison between traditional open and minimally invasive transthoracic resection for oesophageal cancer.

Contacts

Public
De Boelelaan 1117
S.S.A.Y. Biere
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4444444
Scientific
De Boelelaan 1117
S.S.A.Y. Biere
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4444444

Eligibility criteria

Inclusion criteria

1. Histologically proven squamous cell carcinoma, adenocarcinoma or undifferentiated carcinoma of the intrathoracic oesophagus and Siewert I junction tumors which are surgically resectable (T1-3, N0-1, M0);

2. Treatment with neo-adjuvant therapy;

3. Age of the patients must be ≥ 18 and ≤ 75 years;

4. European Clinical Oncology Group (ECOG) performance status of 0, 1 or 2;

5. Written informed consent.

Exclusion criteria

1. Carcinoma of the cervical oesophagus;

2. Prior thoracic surgery;

3. No informed consent is provided.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	160
Type:	Actual

Ethics review

Positive opinion

Date:	02-08-2010
Application type:	First submission

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
NTR-new	NL2346
NTR-old	NTR2452
Other	METC VUmc : HGE2008/003
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Biere SSAY, Cuesta MA, van der Peet DL. Minimally invasive versus open esophagectomy for cancer: a systematic review and meta-analysis. Minerva Chirurgica. 2009; 64: 121-133.