Traditional invasive versus minimally invasive esophagectomy.

Gepubliceerd: 02-08-2010 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20420

Bron
NTR

Verkorte titel
TIME-trial

Aandoening

oesophagectomy, minimally invasive, open, cancer

Ondersteuning

Primaire sponsor: VU university medical center
Overige ondersteuning: initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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

Wetenschappelijk

De Boelelaan 1117
S.S.A.Y. Biere
Amsterdam 1081 HV
The Netherlands

+31 (0)20 4444444

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Carcinoma of the cervical oesophagus;

2. Prior thoracic surgery;

3. No informed consent is provided.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2009
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-08-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2346
NTR-old	NTR2452
Ander register	METC VUmc : HGE2008/003
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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.