ROBOT trial: Robot-assisted minimally invasive thoraco-laparoscopic esophagectomy vs. open transthoracic esophagectomy

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Evaluate the benefits, risks and costs of robot-assisted thoraco-laparoscopic esophagectomy as an alternative to open transthoracic esophagectomy as treatment for esophageal cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41398

Source
ToetsingOnline

Brief title
ROBOT trial

Condition

- Other condition

Synonym
esophageal cancer, esophageal carcinoma

Health condition

Oesofagus carcinoom

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: esophageal cancer, minimally invasive, randomized controlled trial (RCT), robotic surgery, surgical treatment

Outcome measures

Primary outcome

Primary endpoint

Overall morbidity: the percentage of overall complications as staded by the

modified Clavien-Dindo classification grade 2 t/m 5.

Secondary outcome

Secondary endpoints:

Individual components of the primary endpoint.

Oncologic outcomes: disease free survival (recurrence) and overall survival 1,

2, 3 and 5 years after surgery.

Major complications

Including: myocardial infarction, anastomotic leakage, chylothorax (chylous

leakage, presence of chylous in thoraxdrains or indication start Vivonex®,

gastric tube necrosis (proven by gastroscopy), pulmonary embolus, deep vein

thrombosis, vocal cord palsy, pneumonia, atelectasis.

Minor complications

Including: wound infections, pleural effusions, delayed gastric emptying

Operation related events:

Operation time is defined as time from incision until closure (minutes) for each phase of surgery. For the robotic procedure, set up time will de recorded seperatley. Unexpected events and complications occurring during the operation will be recorded (e.g. massive hemorrhage, perforation of other organs).

Blood loss during operation (ml, per phase).

In case of conversion to thoracotomy or laparotomy the reason for conversion has to be explained (absolute numbers/percentage).

Postoperative recovery:

Pain: Type and dose of used analgesics will be noted during the hospital admission period.

Visual Analogue Scale (VAS) will be noted at following times: pre-operatively and the first 10 days after surgery.

Length of ICU-MCU stay (days)

Length of hospital stay (days)

Quality of life

Questionnaires will be required at following times:

SF-36, EORTC QLQ-C30 (Dutch), EORTC OES18 (Dutch) (Appendix 1 & 2)

pre-operative < 5 days, 6 weeks, 6 months and 1, 2 and 3 years post-operatively.

Costs (euro)

Direct general costs, due to extra operating room time andextra instruments.

Indirect costs.

Pathologic examination

The resected specimen will be marked by the surgical team for the position of lymph node dissection. Evaluation will be performed by an experienced pathologist using standard protocols (11, 15). Stage grouping will take place according to the Union Internationale Contre le Cancer (UICC) protocol using the TNM-7 classification. Exact localization of the lymph nodes is an essential part of the pathologic examination. The report by the pathologist should be standardized and contain the following: site of tumor, type and gradation, extension in the esophageal wall, margins of the resection, extent of resection (R0, R1 or R2), lymph node status with the number of lymph nodes and vaso-invasion and perineural growth.

Study description

Background summary

As stated in the 2010 revised Dutch esophageal carcinoma guidelines, the golden standard for surgical treatment of esophageal carcinoma is open transthoracic esophagectomy Recent evidence suggests that robot-assisted thoraco-laparoscopic esophagectomy using the Da Vinci ® robot can provide an extensive resection, with possibly better R0 resection rates and an equal number of dissected lymph nodes. This is accompanied with markedly reduced blood loss and cardiopulmonary complications with shorter ICU and hospital stay. Therefore, the robot-assisted thoraco-laparoscopic esophagectomy is now at a stage that is should be compared to the current standard of care in a randomized controlled trial.

Study objective

Evaluate the benefits, risks and costs of robot-assisted thoraco-laparoscopic esophagectomy as an alternative to open transthoracic esophagectomy as

treatment for esophageal cancer.

Study design

Randomized controlled parallel-group superiority trial

Intervention

112patients will be randomly allocated to either A) robot-assisted thoraco-laparoscopic esophagectomy (n=56) or B) open transthoracic esophagectomy (n=56).
Patients will receive the following interventions:
Group A. Robot-assisted thoraco-laparoscopic esophagectomy, with gastric conduit formation.
Group B. Open transthoracic esophagectomy, with gastric conduit formation.

Study burden and risks

Pulmonary complications (pneumonia, atelectasis), cardiac complications (atrial fibrillation, myocard infarction), anastomotic leakage esophagogastrostomy, recurrent nerve paralysis, chylothorax, wound infection en perioperative death.

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

- Histologically proven squamous cell carcinoma, adenocarcinoma or undifferentiated carcinoma of the intrathoracic esophagus.
- Surgical resectable (T1-4a, N0-3, M0)
- Age * 18 and * 80 years
- European Clinical Oncology Group (ECOG) performance status 0,1 or 2
- Written informed consent

Exclusion criteria

- Carcinoma of the cervical and Siewert III gastro-esophageal junction carinoma (GEJ)
- Prior thoracic surgery

Study design

Design

Study phase:	3
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):	06-02-2012
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	04-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-05-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28386
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT01544790
CCMO	NL35048.041.11
OMON	NL-OMON28386

Study results

Date completed:	15-07-2021
Actual enrolment:	112