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The effect of postoperative 3 month home enteral nutrition on health related quality of life and nutritional status of esophageal cancer patients after receiving Ivor Lewis minimally invasive esophagectomy.

Submission date
16/01/2016

Recruitment status
No longer recruiting

Registration date
01/03/2016

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nutrition support is extremely important for patients suffering from esophageal carcinoma (cancer of the food pipe), as between 60-85% of patients suffer from cachexia (weakness and wasting of the body) and preoperative (before surgery) malnutrition. After undergoing esophagectomy (surgical removal of all or part of the esophagus), people might find it difficult to eat due to complications such as asthenia (physical weakness and lack of energy), pain, anorexia, and problems with digestion. It has been reported that patients require 3 to 9 months to start eating in a regular way again (a defined eating pattern) after esophagectomy. Most patients lose more than 10-15 percent of their body mass index (BMI) within 6 months after the operation and are therefore at severe risk of becoming malnourished, which will adversely affect their quality of life. Early enteral nutrition (for example, by feeding tube) has been demonstrated to lower the risk of surgical complications, such as pneumonia, and has been shown to result in shorter hospital stays after surgery than with parenteral nutrition (intravenous feeding). However, the potential benefits of home enteral nutrition and the effects of home enteral nutrition on quality of life after esophagectomy remain unclear. This study looks at whether early enteral nutrition will improve patients' quality of life and reduce the risk of malnutrition.

Who can participate?
Adults diagnosed with esophageal carcinoma and about to have a esophagectomy.

What does the study involve?
Patients are allocated into one of two groups, depending on the wishes of the patients or surgeons, or due to safety concerns or personal preference. The first group have a surgical procedure called minimally invasive Ivor Lewis esophagectomy and receive enteral nutrition both at the hospital and at home for 3 months. The second group had open esophagectomy and

receive no enteral nutrition once back at home. All patients are assessed for malnutrition and quality of life 3 days before surgery, 2 weeks after surgery and again 3 months after surgery.

What are the possible benefits and risks of participating?
Possible benefits include an improvement in patients' quality of life and a reduction in the risk of malnutrition. A possible risk is the development of a jejunostomy site enterocutaneous fistula.

Where is the study run from?
Second Affiliated Hospital of Zhejiang University School of Medicine (China)

When is the study starting and how long is it expected to run for?
January 2014 to February 2016

Who is funding the study?
Second Affiliated Hospital of Zhejiang University School of Medicine (China)

Who is the main contact?
Professor Ming Wu

Contact information

Type(s)
Scientific

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310009

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Home enteral nutrition after minimally invasive esophagectomy can improve patients' quality of life and reduce the risk of malnutrition.

Study objectives
Early enteral nutrition has been demonstrated to induce lower rates of surgical complications and has been shown to result in shorter postoperative hospital stays than with parenteral nutrition. However, the potential benefits of home enteral nutrition and the effects of home enteral nutrition on quality of life after esophagectomy remain unclear.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Second Affiliated Hospital of Zhejiang University, 15/12/2013

Study design
Single-center interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Nutritional support after esophagectomy

Interventions
Initially, patients were randomly allocated to receive one of the following:
1. MIE group: minimally invasive Ivor Lewis esophagectomy and home enteral nutrition. In this group, patients were trained to give themselves enteral nutrition feeds at home. After discharge, the patients continued with home enteral nutrition with 500-1000kcal/d for 3 months.
2. OE group: patients were allocated to receive open esophagectomy. In this group, no home enteral nutrition was given to these patients after discharge.

However, for ethics reasons, the allocation was permitted to be changed either by patients or by surgeons, due to safety concerns or for personal preference; the trial was therefore non-randomized.

Intervention Type
Mixed

Primary outcome measure
1. The nutritional status, measured using the PG-SGA standard questionnaire, BMI, Albumin and Hemoglobin within 3 days prior to surgery, 2 weeks and 3 months after operation
2. Quality of life, measured using the European Organization for Research and Treatment of Cancer (EORCT) general quality of life questionnaire (QLQ-C30) within 3 days prior to surgery, 2 weeks and 3 months after operation

Secondary outcome measures
1. Outcomes for different surgical procedures , measured using the total hospital stay, time in the ICU, morbidity and mortality within 30 days
2. Pain after surgery, measured using visual analogue score (VAS) until day 3 after surgery
3. Complications after surgery, measured using pneumonia, chylothorax, vocal-cord paralysis, wound infection needing reoperation, anastomotic leakages, cardiac insufficiency, ileus need stop enteral nutrition and jejunostomy site enterocutaneous fistula
4. Pathological results, measured using pathological tumor-node-metastasis classification, resection and circumferential margins and the number of lymph nodes retrieved

Overall study start date
01/01/2014

Completion date
01/02/2016

Eligibility

Key inclusion criteria
1. Diagnosed with esophageal and esophagogastric junction cancer
2. Deemed suitable for potentially curative resection with intrathoracic anastomosis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
About 70 patients in each group

Key exclusion criteria
1. Patients with unresectable tumors
2. Patient older than 80 years old
3. Patients that needed cervical incision and anastomosis

Date of first enrolment

01/01/2014

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
China

Study participating centre
Second Affiliated Hospital of Zhejiang University School of Medicine
The Department of Thoracic Surgery
No. 88 Jiefang Road
Hangzhou
China
310009

Sponsor information

Organisation
Second Affiliated Hospital of Zhejiang University School of Medicine

Sponsor details
The Department of Thoracic Surgery
No. 88 Jiefang Road
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31000

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/059cjpv64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Second Affiliated Hospital of Zhejiang University School of Medicine (China)

Results and Publications

Publication and dissemination plan

Intention to publish date
01/02/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018	24/01/2019	Yes	No