

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	<input type="checkbox"/> Prospectively registered
Registration date 01/03/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/01/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Contact name

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Additional identifiers

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

<https://ror.org/059cjp64>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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

Results and Publications

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