

# 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.

<b>Submission date</b> 16/01/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/03/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/01/2019	<b>Condition category</b> 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

Prof Ming Wu

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### Contact details

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## Additional identifiers

### Protocol serial number

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

### **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?
<a href="#">Results article</a>	results	01/08/2018	24/01/2019	Yes	No