

Early feeding versus routine feeding after tumor removal using Ivor Lewis minimally invasive esophagectomy

Submission date 02/02/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/03/2020	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Esophageal cancer is a type of cancer affecting the food pipe (esophagus), the long tube that carries food from the throat to the stomach.

In the Ivor Lewis esophagectomy, the esophageal tumor is removed through an abdominal incision and a right thoracotomy (a surgical incision of the chest wall).

The question about how to deal with postoperative feeding after esophageal resection has become an important topic of debate. It has been demonstrated that early oral feeding of patients after thoracoscopic McKeown esophagectomy was feasible and safe. There is no study to test whether early oral feeding policy can be applied after minimally invasive Ivor Lewis intervention with intrathoracic anastomosis.

The aim of this study is to test whether EOF policy (when to eat depending on patients' willingness) can be applied after minimally invasive Ivor Lewis intervention with intrathoracic anastomosis.

Who can participate?

Patients aged ≥ 18 years and ≤ 80 years and undergoing minimally invasive Ivor Lewis intervention with intrathoracic anastomosis for esophageal cancer.

What does the study involve?

Participants will be randomly allocated to either resume feeding seven days after surgery (treatment as usual) or to resume feeding once they request food.

What are the possible benefits and risks of participating?

Shorten the length of hospital stay and improve the quality of postoperative life for patients with esophageal cancer are the benefits. Since this clinical study only changed the postoperative feeding time for patients and the incidence of anastomotic fistula after esophageal cancer has been proved to be independent of feeding time. Therefore, this clinical study does not add additional risk to patients.

Where is the study run from?

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

When is the study starting and how long is it expected to run for?

March 2020 to January 2022

Who is funding the study?

Second Affiliated Hospital of Zhejiang University (China)

Who is the main contact?

Prof. Ming Wu

iwuming22@zju.edu.cn

Contact information

Type(s)

Public

Contact name

Prof Ming Wu

ORCID ID

<http://orcid.org/0000-0002-1009-5387>

Contact details

Second Affiliated Hospital of Zhejiang University

No. 88 Jiefang road

Hangzhou

China

31009

+86 13757118715

iwuming22@zju.edu.cn

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2019-383

Study information

Scientific Title

A randomized clinical trial to assess early feeding versus routine feeding for patients who undergo Ivor Lewis minimally invasive esophagectomy

Study objectives

The aim of this study is to test whether EOF policy (when to eat depending on patients' willingness) can be applied after minimally invasive Ivor Lewis intervention with intrathoracic anastomosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/11/2019, Ethics Committee of the Second Affiliated Hospital of Zhejiang University (No. 88 Jiefang road, Hangzhou city, Zhejiang province, China, 310009; +86 0571-87783759; HREC2013@126.com;), ref: 2019-383

Study design

Single-center randomized study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Postoperative feeding after esophageal resection

Interventions

Patients were randomly allocated by a computer-generated random number list to receive EOF policy (when to eat depending on patients' willingness) or LOF (feeding on 7 days after surgery). All the patients underwent minimally invasive Ivor Lewis esophagectomy with 2-field lymph node dissection. Both the groups were treated similarly in the perioperative period.

1. In the EOF group, when the patient complained that he needed to take water or food, then he will be given oral meal solution. After exclude no anastomotic fistula, the patient will be given postoperative diet

2. In the LOF group, on POD7 esophagography will be performed to exclude anastomotic fistula, and postoperative diet was gradually opened

On the first day of feeding, patients received only water, each time 20-50 ml; if there is no discomfort, on the second day slag-free liquid diet will be received, each time 20-50 ml; if there is no discomfort, on the three day after feeding, transition to a semi-flow diet, mainly porridge, 200 ml each time.

Intervention Type

Behavioural

Primary outcome measure

Number of hospital stays after operation. The discharge criteria are: ability to tolerate a soft diet, no signs of a postoperative complication that needed to be treated at the hospital, ability to ambulate without assistance, tolerable pain on oral analgesia and assessed by the attending doctor

Secondary outcome measures

1. Quality of life, measured using the European Organization for Research and Treatment of Cancer (EORTC) assessed within 3 days prior to surgery, 2 weeks , 4 weeks and 3 months after operation
2. General quality of life questionnaire (C30) and OES18 assessed within 3 days prior to surgery, 2 weeks , 4 weeks and 3 months after operation
3. Time in the ICU, morbidity (graded based on the Clavien–Dindo classification)
4. Mortality within 30 days

Overall study start date

01/02/2020

Completion date

31/01/2022

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years
2. Undergoing minimally invasive Ivor Lewis intervention with intrathoracic anastomosis for esophageal cancer

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60 patients in each group

Key exclusion criteria

1. Age \geq 80 years
2. Exploratory surgery
3. Bilateral recurrent laryngeal nerve (RLN) injury
4. Patients with other malignancies

Date of first enrolment

01/03/2020

Date of final enrolment

31/12/2021

Locations**Countries of recruitment**

China

Study participating centre

Second Affiliated Hospital of Zhejiang University

No. 88 Jiefang road

Hangzhou

China

31009

Sponsor information**Organisation**

Second Affiliated Hospital of Zhejiang University

Sponsor details

No. 88 Jiefang road

Hangzhou

China

31009

+86 13757118715

iwuming22@zju.edu.cn

Sponsor type

Hospital/treatment centre

Website

<http://en.z2hospital.com/>

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Zhejiang University

Alternative Name(s)

, , Chekiang University, Chekiang Higher Institutes, National Third Chungshan University, National Chekiang University, ZJU, NCKU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

China

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/01/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request