ISRCTN16281941 https://doi.org/10.1186/ISRCTN16281941

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

Submission date
02/02/2020

Recruitment status
No longer recruiting

Registration date
19/02/2020

Overall study status
Completed

Last Edited
03/03/2020

Condition category
Surgery

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 esphagectomy, 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 thoracolaparoscopic 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 meilan 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 (EORCT) 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 ≥ 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/059cjpv64

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