

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

A comparison of perioperative short outcomes between patients' different positions in thoracoscopic-laparoscopic esophagectomy for patients with esophageal cancer th esophageal cancer

Protocol summary

Study aim

Comparison of postoperative outcomes of prone, semi-prone and lateral decubitus positions in thoracoscopic-laparoscopic esophagectomy of patients with esophageal cancer referred to Imam Reza hospital between 2018-2020

Design

A clinical trial with 3 groups, randomized, single-blind, on 51 patients using simple random sampling method.

Settings and conduct

In this clinical trial study, 51 patients with cancer referred to Imam Reza (AS) hospital in Tabriz between 2018-2020, who are willing to undergo upper endoscopy and biopsy and approved, will be included in the study. Staging and surgical intervention in patients will be performed by CT-Scan with chest and abdomen contrast and bronchoscopy (for middle third tumors). For all Chest X-Ray patients, lung function tests, ECG and cardiovascular function will be performed. The surgeon will not know the type of position before entering the operating room, and upon entering the operating room, the relevant nurse will randomly announce the type of surgical position to the surgeon based on the list prepared and those who evaluate the consequences of surgery will not know the type of position and goals of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction to participate in the study and esophageal cancer Exclusion criteria: Sensitivity to anesthetics and impossibility of anesthesia and death of the patient during surgery

Intervention groups

Patients will be randomly divided into 3 groups: prone position, semi-prone position and lateral decubitus. Patients will then undergo MIE.

Main outcome variables

Intraoperative variables (duration of surgery, rate of

blood loss, likelihood of change to open surgery) and postoperative variables (mortality, morbidity: respiratory complications, esophagogastric anastomotic leakage, thoracic duct injury, hoarseness)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200703047990N1**

Registration date: **2020-08-25, 1399/06/04**

Registration timing: **retrospective**

Last update: **2020-08-25, 1399/06/04**

Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Hossein Ostadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3440 5872

Email address

hostadi2005@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

2019-10-23, 1398/08/01
Actual recruitment end date
2020-04-20, 1399/02/01
Trial completion date
2020-04-20, 1399/02/01

Scientific title
A comparison of perioperative short outcomes between patients' different positions in thoracoscopic-laparoscopic esophagectomy for patients with esophageal cancer th esophageal cancer

Public title
Evaluation of three methods of thoracoscopic-laparoscopic esophagectomy in esophageal cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Satisfaction to participate in the study Having esophageal cancer
Exclusion criteria:
Allergy to anesthetics Inability to anesthetize the patient

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider

Sample size
Target sample size: **50**
Actual sample size reached: **51**

Randomization (investigator's opinion)
Randomized

Randomization description
We selected 51 patients from 150 patients using a random number table. For this, each patient was assigned a three-digit code, then 3 groups were selected randomly using random numbers table by closed eyes. First we assigned the selected numbers to the first group, then to the second group and reminders go to the third group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The surgeon is not aware of the patient's position before the operation

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

No. 15, Varzesh Ave, Dampezeshki Ave, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5183838436

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.TBZMED.REC.1399.317

Health conditions studied

1

Description of health condition studied

Esophageal cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood loss

Timepoint

Immediately after and 24 hours after surgery

Method of measurement

milliliter

2

Description

Surgical satisfaction(Probability of change to open surgery)

Timepoint

After the intervention

Method of measurement

Satisfaction Questionnaire

3

Description

Duration of surgery

Timepoint

Before the intervention until the end of surgery

Method of measurement

The number of hours surgery takes

4

Description

Mortality

Timepoint

After the intervention

Method of measurement

check list

5

Description

Morbidity

Timepoint

After the intervention

Method of measurement

check list

6

Description

respiratory complications

Timepoint

after surgery

Method of measurement

clinical assesment and imaging

7

Description

leak of esophagogastric anastomosis

Timepoint

after surgery

Method of measurement

clinical assesment and imaging

8

Description

thoracic duct injury

Timepoint

after surgery

Method of measurement

clinical assesment

9

Description

hoarsness

Timepoint

after surgery

Method of measurement

clinical assesment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: prone position

Category

Treatment - Surgery

2

Description

Intervention group: semi prone position

Category

Treatment - Surgery

3

Description

Intervention group: lateral decubitus

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center**Name of recruitment center**

Emam Reza hospital

Full name of responsible person

Hosein Ostadi

Street address

No. 15, Varzesh Ave, Dampeszehki Ave, Tabriz

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Email

hostadi2005@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hosein Ostadi

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Email

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Grant name**Grant code / Reference number**

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hosein Ostadi

Position

Non-faculty specialist

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Scientific research use

From where data/document is obtainable

For information, please contact hostadi2005@gmail.com and call 09144143697 in the name of Mr. Hossein Ostadi.

What processes are involved for a request to access data/document

3 to 6 months after receiving the request

Comments