# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparison of two methods of patient-controlled analgesia through intravenous and thoracic epidural to control pain and complications after surgery in esophageal cancer patients at the Cancer Institute of Imam Khomeini Hospital

## Protocol summary

**Study aim**
Determining the difference between patient-controlled analgesia intravenously and thoracic epidural to control pain and complications after surgery in esophageal cancer patients

**Design**
Patients seeking esophageal cancer surgery were included in the study divided into two groups. The even file numbers of block A and odd were placed in block B. One group was implanted from the thoracic space (T6-8 level) before the start of epidural anesthesia and in the last half hour of the operation, an epidural analgesic pump with local anesthetic bupivacaine 0.125% - 4ml / hr was implanted and the other group after implantation. Anesthesia was connected to a peripheral vein pump at half an hour after the end of the operation and they underwent intravenous infusion of morphine 10mcg / kg / hr and ketorolac 120 mg / day. Pain and complications after surgery were compared.

**Settings and conduct**
The study was performed in the ICU and operating room of Imam Khomeini Hospital in Tehran. No blinding was performed in this study.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients who are candidates for esophageal cancer surgery. Non-entry conditions: coagulation disorders, neurological disorders, movement disorders, drug addiction

**Intervention groups**
Intervention group 1: The group that was implanted from the thoracic space before the epidural anesthesia was started and in the last half hour of the epidural analgesia pump with local anesthesia was implanted. Intervention group: The group that was connected to the patient from the peripheral vein after half anesthesia at the end of the operation and the patient underwent intravenous infusion

**Main outcome variables**
Second day postoperative pain; Third day postoperative pain; Duration of hospitalization in the ICU; Extra drug use required; Quarterly survival rate; Systolic blood pressure; Diastolic blood pressure; Pulse count

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200929048879N1**
Registration date: **2020-12-06, 1399/09/16**
Registration timing: **retrospective**

Last update: **2020-12-06, 1399/09/16**
Update count: **0**

**Registration date**
2020-12-06, 1399/09/16

**Registrant information**

**Name**
Maziar Maghsoudloo

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-03-19, 1398/12/29

**Expected recruitment end date**

2020-12-20, 1399/09/30

**Actual recruitment start date**

2019-04-21, 1398/02/01

**Actual recruitment end date**

2020-04-30, 1399/02/11

**Trial completion date**

2020-04-30, 1399/02/11

**Scientific title**

Comparison of two methods of patient-controlled analgesia through intravenous and thoracic epidural to control pain and complications after surgery in esophageal cancer patients at the Cancer Institute of Imam Khomeini Hospital

**Public title**

Comparison of two methods of patient-controlled analgesia through intravenous and thoracic epidural in surgery of esophageal cancer patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients who have referred for esophageal cancer surgery. Patients in the age range of 20 to 80 years who were candidates for esophageal cancer surgery.

**Exclusion criteria:**

Patients with coagulation disorders. Infection of the epidural catheter insertion site Patients with severe hemodynamic disorders. Patients with severe movement disorders. Patients with chest disorders. Patients with neurological disorders. Patients who are addicted to drugs.

**Age**

From **20 years** old to **80 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

Actual sample size reached: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Candidate patients for esophageal cancer surgery were divided into two groups by random blocking and using a random number table. The even number of files will be in block A and the odd number in block B. To read counting numbers from top to bottom. Out of 80 randomly selected patients, 40 patients will be implanted in block A before the onset of epidural catheter anesthesia from the thoracic space and an epidural analgesic pump with local anesthetic will be implanted for patients around the end of the operation and 40 patients in block B After anesthesia and surgery near the end of the operation, a venous pump was connected to the peripheral vein for the patients and the patients will undergo intravenous infusion of narcotics and ketorolac. At the end, the two groups will be compared in terms of pain control and short-term complications.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Headquarters of Tehran University of Medical Sciences, corner of Ghods St, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1997663786

**Approval date**

2018-07-21, 1397/04/30

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1397.199

## Health conditions studied

### 1

**Description of health condition studied**

Control of pain and complications after surgery in esophageal cancer patients

**ICD-10 code**

MG30.10

**ICD-10 code description**

Chronic cancer pain

## Primary outcomes

### 1

**Description**

Control of pain and complications after surgery in patients undergoing esophageal cancer surgery according to the Global Pain Assessment Tool (UPAT)

**Timepoint**

Before and during esophageal cancer surgery and during hospitalization in the ICU

**Method of measurement**

Using the Global Pain Assessment Tool (UPAT)

**2**

**Description**
Pain score on the second day after esophageal cancer surgery with Global Pain Assessment Tool (UPAT)
**Timepoint**
During hospitalization in the ICU
**Method of measurement**
Using the Global Pain Assessment Tool (UPAT)

**3**

**Description**
Pain score on the third day after esophageal cancer surgery with Global Pain Assessment Tool (UPAT)
**Timepoint**
During hospitalization in the ICU
**Method of measurement**
Using the Global Pain Assessment Tool (UPAT)

**4**

**Description**
Determining the length of hospital stay of patients in the ICU
**Timepoint**
During hospitalization in the ICU until transfer to the surgical ward
**Method of measurement**
Clinical symptoms of patients

**5**

**Description**
Extra drug use required based on patients' pain score
**Timepoint**
After esophageal cancer surgery and during hospitalization in the ICU
**Method of measurement**
Using the Global Pain Assessment Tool (UPAT)

**6**

**Description**
Quarterly survival rate
**Timepoint**
After surgery up to three months after discharge from the hospital
**Method of measurement**
Examination of the patient and questions and answers from the patient

**7**

**Description**
Systolic blood pressure
**Timepoint**
During surgery until the patient is discharged from the hospital
**Method of measurement**
Mercury sphygmomanometer

**8**

**Description**
Diastolic blood pressure
**Timepoint**
During surgery until the patient is discharged from the hospital
**Method of measurement**
Mercury sphygmomanometer

**9**

**Description**
Count the pulse
**Timepoint**
During surgery until the patient is discharged from the hospital
**Method of measurement**
Through standard patient heart rate monitoring

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Patients who have had a thoracic catheter implanted before the epidural anesthesia and an epidural analgesic pump with a local anesthetic will be inserted around the end of the operation.
**Category**
Treatment - Devices

**2**

**Description**
Intervention group: Patients who after anesthesia and surgery near the end of the venous pump from the peripheral vein is connected to the patient and the patient will undergo intravenous infusion of narcotics and ketorolac
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Imam Khomeini Hospital
**Full name of responsible person**
Sina Abbasi
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Keshavarz Blv, Gharib St, Imam Khomeini Hospital Complex
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Shahin Akhundzadeh
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Corner of Ghods St, Keshavarz Blvd, Central Organization of Tehran University of Medical Sciences
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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**
Tehran 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**
Tehran University of Medical Sciences
**Full name of responsible person**
Sina Abbasi
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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**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable