Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Investigating the effect of dexmedetomidine in preventing delirium after esophagectomy surgery

Protocol summary

Study aim
Investigating the effect of dexmedetomidine in preventing delirium after esophagectomy surgery

Design
In this double-blind clinical trial study (participants and results analyzer), patients will undergo surgery after random allocation in the two mentioned groups. For one group, dexmedetomidine drug will be injected intravenously, and for the other group, normal saline will be injected intravenously, agitation after surgery will be compared between the two groups.

Settings and conduct
This study was conducted as a randomized clinical trial (blocks of four), double blind (participants and results analyzer), with parallel groups, without a control group and with the participation of 60 patients with esophagectomy surgery referred to Imam Reza Hospital (Tabriz).

Participants/Inclusion and exclusion criteria
The criteria for entering the study include: candidate for esophagectomy surgery, duration of surgery between three to five hours and the same anesthesia method for all patients, and exclusion criteria also include: ASA class higher than III, body mass index greater than 30, heart rate less than 50 times per minute and sensitivity to dexmedetomidine.

Intervention groups
In this study, patients who will refer to the operating room due to esophagectomy surgery will be subjected to intervention. Patients will be randomly divided into two groups. For one group, dexmedetomidine drug will be injected intravenously, and for the other group, normal saline will be injected intravenously, agitation after surgery will be compared between the two groups.

Main outcome variables
Agitation

General information

Reason for update
Hello and greetings, Respectfully, the number of samples was mistakenly entered as 80 instead of 60 during the registration in the trial system, which has now been corrected.

Acronym

IRCT registration information
IRCT registration number: **IRCT20190325043107N42**
Registration date: **2024-01-07, 1402/10/17**
Registration timing: **prospective**

Last update: **2024-10-27, 1403/08/06**
Update count: **1**

Registration date
2024-01-07, 1402/10/17

Registrant information

Name
Mehdi Khanbabayi Gol

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 7054

Email address
khanbabayimehdi69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-19, 1402/10/29

Expected recruitment end date
2025-01-18, 1403/10/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of dexmedetomidine in preventing delirium after esophagectomy surgery

Public title
Investigating the effect of dexmedetomidine in preventing delirium after esophagectomy surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for esophagectomy surgery The duration of the surgery is between three and five hours Same anesthesia method for all patients

Exclusion criteria:
Body mass index greater than 30 ASA class above III Heart rate less than 50 beats per minute Allergy to dexmedetomidine

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, with a sample size of 60, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 15 blocks for 60 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they will divid into two intervention groups (group A) and control group (group B).

Blinding (investigator's opinion)
Double blinded

Blinding description
The thesis results analyst who will analyze the expected result and also the participants will be unaware of the type of procedure performed and will be blind during the study; Therefore, this study will be conducted in a double-blind manner. Since the participants will be unaware of the type of drug used, in this study they will not know what type of drug will be used in other patients.

Placebo
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
Imam Reza Hospital, Azadi Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5165665631

Approval date
2023-12-18, 1402/09/27

Ethics committee reference number
IR.TBZMED.REC.1401.859

Health conditions studied

1

Description of health condition studied
Agitation

ICD-10 code
R45.1

ICD-10 code description
Restlessness and agitation

Primary outcomes

1

Description
Agitation

Timepoint
Three times in three days and once every day

Method of measurement
Examination by a neurologist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will be randomly assigned to

this group. Immediately after the induction of anesthesia, the patients will receive the intervention. Dexmedetomidine will be injected at a rate of 0.5 micrograms/kg per hour. The drug infusion will continue until the end of the surgery (the end of the surgical dressing). Finally, the degree of delirium will be measured once every 24 hours for all patients until the third day after discharge from the operating room.

Category

Prevention

2

Description

Control group: Patients will be randomly assigned to this group. Immediately after the induction of anesthesia, the patients will receive the intervention. Normal saline injection will be done at a rate of 0.5 ml/kg per hour. The drug infusion will continue until the end of the surgery (the end of the surgical dressing). Finally, the degree of delirium will be measured once every 24 hours for all patients until the third day after discharge from the operating room.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Mahmoud Eydi

Street address
Imam Reza Hospital, Azadi Ave

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Tabriz

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6165665631

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Abolghasem Jouyban

Street address
Imam Reza Hospital, Azadi Ave

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Ajouyban@hotmail.com

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
Mehdi Khanbabayi Gol

Position
MSc in Nursing Education

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

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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)

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

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

Undecided - It is not yet known if there will be 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