Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the preventive effect of two different doses of dexmedetomidine on the incidence of cough and respiratory complications during extubation compared to the control group.

Protocol summary

Study aim

General aim: to determine the preventive effect of two different doses of dexmedetomidine on the occurrence of cough and respiratory complications during tracheal tube removal compared to the control group

Design

A clinical trial with a control group, with parallel groups, three blind strains, randomized, phase 2 and 3 on 105 patients. Random allocation statistical software was used for randomization.

Settings and conduct

The present study is a three-blind randomized clinical trial that will be conducted at Ayatollah Kashani Medical Center. In this study, there are two intervention groups and one control group, and people are randomly assigned to these groups. The intervention method is described above. The study participants, the person who collects the data, and the data analyst are not aware of the study groups

Participants/Inclusion and exclusion criteria

Entry criteria: age between 18-65 years, ASA 1,2, need general anesthesia with tracheal intubation Exclusion criteria: patients with heart failure, respiratory failure, renal failure, hepatic failure, known allergy to the studied drugs, heart block, uncontrolled blood pressure, smokers and addiction to any type of addictive substance

Intervention groups

Group 1: 0.5 µg/kg dexmedetomidine bolus followed by 0.3 µg/kg infusion, ten minutes before tracheal tube removal. Group 2: 0.5 µg/kg dexmedetomidine bolus followed by 0.5 µg/kg infusion, ten minutes before tracheal tube removal. Group 3 (control): 10 minutes before leaving the tracheal tube, normal saline is injected with an equal volume of groups one and two as a bolus, and then with an equal volume of the other two groups as an infusion.

Main outcome variables

The frequency of coughing and the intensity of coughing during extubation, which is recorded from the time of full awakening to 5 minutes after extubation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090129001615N8**
Registration date: **2023-05-13, 1402/02/23**
Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**
Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name

Azim Honarmand

Name of organization / entity

Alzahra hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the preventive effect of two different doses of dexmedetomidine on the incidence of cough and respiratory complications during extubation compared to the control group.

Public title

Investigating the effective dose of dexmedetomidine in preventing cough during extubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 65 years ASA1,2 need general anesthesia with tracheal intubation

Exclusion criteria:

Patients with heart failure Patients with respiratory failure Patients with renal failure Patients with hepatic failure Previous known allergy to study drugs heart block Uncontrolled blood pressure smokers Addiction to any type of addictive substance

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random allocation software, patients are divided into three groups

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study participants, the person who collects the data, and the data analyst are not aware of the study groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jarib Ave., Isfahan university of medical sciencies

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.MUI.MED.REC.1402.047

Health conditions studied

1

Description of health condition studied

respiratory complications during extubation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Frequency of coughing during extubation

Timepoint

From the time of full awakening to 5 minutes after extubation

Method of measurement

Using direct observation, the occurrence or non-occurrence of cough is recorded

2

Description

severity of cough

Timepoint

From the time of full awakening to 5 minutes after extubation

Method of measurement

Minogue scale

Secondary outcomes

1

Description

Determination and comparison of systolic blood pressure in three groups

Timepoint
5 minutes before the end of surgery, at the end of surgery, at the time of awakening, at the time of extubation, 2 minutes and 5 minutes after extubation, at the time of entering recovery and 10 minutes after recovery
Method of measurement
Dial sphygmomanometer

2

Description
Determination and comparison of diastolic blood pressure in three groups
Timepoint
5 minutes before the end of surgery, at the end of surgery, at the time of awakening, at the time of extubation, 2 minutes and 5 minutes after extubation, at the time of entering recovery and 10 minutes after recovery
Method of measurement
Dial sphygmomanometer

3

Description
Determination and comparison of mean arterial pressure in three groups
Timepoint
5 minutes before the end of surgery, at the end of surgery, at the time of awakening, at the time of extubation, 2 minutes and 5 minutes after extubation, at the time of entering recovery and 10 minutes after recovery
Method of measurement
Dial sphygmomanometer

4

Description
Determination and comparison of heart rate in three groups
Timepoint
5 minutes before the end of surgery, at the end of surgery, at the time of awakening, at the time of extubation, 2 minutes and 5 minutes after extubation, at the time of entering recovery and 10 minutes after recovery
Method of measurement
pulse oximeter

5

Description
Determination and comparison of respiratory rate in three groups
Timepoint
5 minutes before the end of surgery, at the end of surgery, at the time of awakening, at the time of extubation, 2 minutes and 5 minutes after extubation, at the time of entering recovery and 10 minutes after recovery
Method of measurement
observation

6

Description
Determining and comparing the average dose of lidocaine and fentanyl used to control cough
Timepoint
From the time of full awakening to 5 minutes after extubation
Method of measurement
observation

7

Description
Determining and comparing the average dose of labetalol used in three groups
Timepoint
From the time of full awakening to 5 minutes after extubation
Method of measurement
observation

8

Description
Determining and comparing the average duration of surgery and anesthesia and stay in recovery in three groups
Timepoint
From the beginning of surgery to exit from recovery
Method of measurement
observation

9

Description
Determining and comparing the average dose of ondansetron consumed in three groups
Timepoint
From the time of full awakening to 5 minutes after extubation
Method of measurement
observation

10

Description
Determination and comparison of pain intensity in three groups
Timepoint
Every 15 minutes in recovery until leaving it
Method of measurement
Visual Analogue Scale

11

Description
Determining and comparing the frequency of nausea and vomiting in three groups
Timepoint
Every 15 minutes in recovery until leaving it

Method of measurement
observation

12

Description
Determining and comparing the average duration of extubation in three groups
Timepoint
At the time of extubation
Method of measurement
observation

13

Description
Determining and comparing the average level of consciousness in three groups
Timepoint
at 2 minutes and 5 minutes after extubation, at the time of entering recovery and 10 minutes after recovery
Method of measurement
Using a 4-point scale, 0=sleepy and unresponsive 1=sleepy but can be woken up 2=sleepy but opens eyes with voice command 3=fully alert

Intervention groups

1

Description
Intervention group 1: 0.5 µg/kg of dexmedetomidine is injected as a bolus and then 0.3 µg/kg of dexmedetomidine is injected as an infusion, ten minutes before the endotracheal tube is removed.
Category
Treatment - Drugs

2

Description
Intervention group2: 0.5 µg/kg of dexmedetomidine is injected as a bolus and then 0.5 µg/kg of dexmedetomidine is injected as an infusion, ten minutes before the endotracheal tube is removed.
Category
Treatment - Drugs

3

Description
Control group: 10 minutes before remove the tracheal tube, normal saline is injected with an equal volume of groups 1 & 2 as a bolus and then with an equal volume of the other two groups as an infusion. It is necessary to explain that if a patient in this group has a continuous cough, tachycardia with heart rate above 100 times per minute, blood pressure increase to systolic pressure above 140 and diastolic pressure above 90 mm Hg, lidocaine with a dose of 1.5 mg/kg is used for control, if there is no response to lidocaine fentanyl It is injected at a dose of 2 µg/kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Azim Honarmand
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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