

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of Dexmedetomidine and Lidocaine to cough suppression after anesthesia

Protocol summary

Study aim

Comparison of Dexmedetomidine and Lidocaine to cough suppression after anesthesia

Design

This study is clinical trial and double blind.102 patients candidates general anesthesia in valiasr hospital will enter. We divide patients in 3 groups with simple randomization.It has a control group.We inject Dexmedetomidin and Lidocain and placebo in 3 groups.

Settings and conduct

This study is clinical trial and double blind.102 patients candidates for general anesthesia in valiasr hospital will enter. We divide patients in 3 groups with simple randomization.This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind).Outcome evaluator and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria:20 to 60 years old, ASA class I and II,Mallampathi class I and II,no addiction,no smoking,Non-activated airway infections or history of surgery and pathology of the chest and larynx,Lack of inadequacy of the esophagus sphincter (no reflux),body mass index more than 30,Lack of increased Intracranial pressure and intraocular pressure,Duration of surgery is between 60 - 120 minutes Exclusion criteria:Lack of satisfaction of patients,Lack of pulmonary and heart disease,No use Medications creates a cough

Intervention groups

We infuse 0/5 micro gram in kilogram Dexmedetomidine(PFIZER [America]) in 10 milliliter of volume for 10 minute before extubation in intervention group1. Intervention group2: We infuse 1/5 milligram in kilogram Lidocaine (Aboreihan Co) in 10 milliliter of volume for 10 minute in Lidocaine group. We infuse 10 milliliter normal saline for 10 minute in placebo group after extubation.

Main outcome variables

cough, larangospasm, duration of surgery, blood

pressure, heart rate, percent of oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N97**

Registration date: **2019-02-22, 1397/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**

Update count: **0**

Registration date

2019-02-22, 1397/12/03

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Dexmedetomidine and Lidocaine to cough suppression after anesthesia

Public title

Comparison of Dexmedetomidine and Lidocaine to cough suppression after anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20 to 60 years old ASA class I and II Mallampathi class I and II no addiction no smoking Non-activated airway infections or history of surgery and pathology of the chest and larynx Lack of inadequacy of the esophagus sphincter (no reflux) body mass index more than 30 Lack of increased Intracranial pressure and intraocular pressure Duration of surgery is between 60 - 120 minutes

Exclusion criteria:

Lack of satisfaction of patients Lack of pulmonary and heart disease No use Medications creates a cough

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random number table in division of groups in two groups A and B. Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment: Numbered drug containers

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer

and outcome assessor.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee Arak University Of Medical Sciences

Street address

Vice President of Research, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.ARAKMU.REC.1397.140

Health conditions studied**1****Description of health condition studied**

Patients candidates general anesthesia

ICD-10 code

Y48.4

ICD-10 code description

Anaesthetic, unspecified

Primary outcomes**1****Description**

Cough

Timepoint

Extubation time and Tenth minute and in the recovery until 40 minutes after removing the tracheal tube

Method of measurement

observation

2**Description**

Laryngospasm

Timepoint

Extubation time and Tenth minute and in the recovery until 40 minutes after removing the tracheal tube

Method of measurement

observation

3**Description**

duration of surgery

Timepoint

after intervention

Method of measurement

minute

4**Description**

Percent of oxygen saturation

Timepoint

Immediately after extubation and then every 5 minutes to 40 minutes after the tube exits

Method of measurement

Pulse oximeter

5**Description**

Blood pressure

Timepoint

Every 10 minutes to 40 minutes after the extubation of the tracheal tube

Method of measurement

Barometer

6**Description**

Heart rate

Timepoint

Every 10 minutes to 40 minutes after the extubation of the tracheal tube

Method of measurement

Count

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: We infuse 0/5 micro gram in kilogram Dexmedetomidine(PFIZER [America]) in 10 milliliter of volume for 10 minute before extubation in intervention group.

Category

Treatment - Drugs

2**Description**

Intervention group 2: We infuse 1/5 milligram in kilogram Lidocaine(Aboreihan Co) in 10 milliliter of volume for 10

minute before extubation in Lidocaine group.

Category

Treatment - Drugs

3**Description**

Control group: We infuse 10 milliliter normal saline for 10 minute in placebo group after extubation.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Hesamodin Modir

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

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

Arak 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
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Full name of responsible person
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Assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Modir

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

They have to write letters to the professors and the

university
Comments