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 Committe 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
Street address
Valiasr hospital, Valiasr squre
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Arak
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3848176941
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+98 86 3222 2003
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
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Research Deputy, Payambar Azam Complex, Basij square, Sardasht, Arak
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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
Arak University of Medical Sciences

Full name of responsible person
dr Bijan Yazdi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr Hesamedin Modir

Position
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Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
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Soheila Saeedi

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Medicine student

Latest degree
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General Practitioner

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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