Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Dexmedetomidine , Lidocaine , Magnesium Sulfate and Remifentanil on stimulatory responses and cough suppression during tracheal tube removal among patients under general anesthesia

Protocol summary

Study aim

Comparison of Dexmedetomidine, Lidocaine, Magnesium Sulfate and Remifentanil to reduce stimulatory responses and cough suppression when tracheal tube removal

Design

The double blind randomized clinical trial, consisted of 120 patients who are randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

The study population are patients undergoing general anesthesia, attending Valiasr hospital in Arak who are divided into 4 groups by simple randomization using envelopes. The study is double-blind in which outcome evaluator, data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being at the age of 20 to 60 years old, ASA class 1 and 2, Malampati class I and II, Both gender, Not smoking, Not addicted, Lack of active airway infection or having a history of surgery and pathology of the chin and larynx, Body mass index less than 30, the duration of surgery is between 60 and 120 minutes
Exclusion criteria: Dissatisfaction of patients, lung and heart disease, not taking cough medicines, esophageal sphincter insufficiency and (lack of reflux), increased intracranial pressure and intraocular pressure

Intervention groups

Intervention group 1: infusion of 0.5 microgram/kilogram Dexmedetomidine slowly in 10 minutes. Intervention group 2: infusion of 1.5 milligram/kilogram Lidocaine slowly in 10 minutes. Intervention group 3: infusion of 1 microgram/kilogram Fentanyl slowly in 10 minutes. Intervention group 4: infusion of 30 milligram/kilogram magnesium sulphate slowly in 10 minutes.

Main outcome variables

Cough, laryngospasm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N149**
Registration date: **2020-09-23, 1399/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-23, 1399/07/02**
Update count: **0**

Registration date

2020-09-23, 1399/07/02

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

2020-06-09, 1399/03/20

Expected recruitment end date

2021-06-10, 1400/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Dexmedetomidine , Lidocaine , Magnesium Sulfate and Remifentanil on stimulatory responses and cough suppression during tracheal tube removal among patients under general anesthesia

Public title
Comparison of Dexmedetomidine , Lidocaine , Magnesium Sulfate and Remifentanil on cough suppression during tracheal tube removal

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 20 to 60 years ASA class 1 and 2 Malampati class l and ll Body mass index less than 30 The duration of surgery is between 60 and 120 minutes
Exclusion criteria:
Dissatisfaction of patients lung and heart disease Take cough medicines Active airway infection or having a history of surgery and pathology of the chin and larynx Esophageal sphincter insufficiency and (lack of reflux) Increased intracranial pressure and intraocular pressure

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with envelopes into 4 groups of A; B; C and D. In this method, we write some letters on the cards as intervention groups and the same numbers on the cards for the control group, then the cards are mixed. One card is taken out and its allocation is registered and the card is returned to the other cards after leaving. Then the cards are mixed again and another card is picked up. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Outcome elevator and analyzer and participant are blind. Outcome elevator and analyzer and participant don't aware of grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij square ,Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941

Approval date
2020-06-07, 1399/03/18

Ethics committee reference number
IR.ARAKMU.REC.1399.093

Health conditions studied

1

Description of health condition studied
General anesthesia

ICD-10 code
T88.4

ICD-10 code description
Failed or difficult intubation

Primary outcomes

1

Description
Cough

Timepoint
At the beginning of the study and then every 5 minutes to 40 minutes

Method of measurement
Observation

2

Description
Laryngospasm

Timepoint
At the beginning of the study and then every 5 minutes to 40 minutes

Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: We infuse 0.5 microgram/kilogram Dexmedetomidine (Exir company, Tehran, Iran) slowly during 10 minutes.
Category
Treatment - Drugs

2

Description
Intervention group 2: We infuse 1.5 milligram/kilogram Lidocaine (Caspian company, Rasht; Iran) slowly during 10 minutes.
Category
Treatment - Drugs

3

Description
Intervention group 3: We infuse 1 micro gram in kilogram Fentanyl (Normon,S.A company; Madrid; Spain) slowly in 10 minutes.
Category
Treatment - Drugs

4

Description
Intervention group 4: We infuse 30 milligram/kilogram magnesium sulphate 20% (Shahid Ghazi company, Tabriz, Iran) slowly during 10 minutes.
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 square
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3848176941
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Research Center, 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 Esmaeel Moshiri
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
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
Title and more details about the data/document
Age, sex, information on cough and laryngospasm and any other information that is collected and analyzed
When the data will become available and for how long
After finishing the work
To whom data/document is available
Researchers
Under which criteria data/document could be used
Research
From where data/document is obtainable
Dr. Hesamodin Modir
What processes are involved for a request to access data/document
Correspondence via email modir.he@gmail.com
Comments