

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of nebulized lidocaine 2% in patients sedation during awake intubation

Protocol summary

Study aim

The aim of this study is evaluation of nebulized lidocaine 2% in patients sedation during awake intubation.

Design

A phase 3 randomized clinical trial with 55 patients

Settings and conduct

Patients will receive 2% nebulized lidocaine with a dose of 3 mg/kg and 6 Lit/min flow rate for 10 minutes. After 5 minutes, the intubation will be done. Determine the depth of sedation will be done in 3 minutes after sedation with midazolam and 10 min after nebulized lidocaine 2% by BIS index monitoring.

Participants/Inclusion and exclusion criteria

Inclusion criteria are candidates to undergo intubation in awake, history of difficult intubations, patients over 14 years of age and below 70 years. Exclusion criteria are patient's lack of cooperation (if the awake intubation is not essential), history of liver and kidney disease and coagulation, pathology of the respiratory tract, pregnancy, patients who have long received opioid or sedative medications and aspiration and regurgitation probability.

Intervention groups

The intervention group is patients who receive nebulized lidocaine 2%.

Main outcome variables

The sedation of patients in awake intubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180806040724N2**

Registration date: **2019-01-01, 1397/10/11**

Registration timing: **prospective**

Last update: **2019-01-01, 1397/10/11**

Update count: **0**

Registration date

2019-01-01, 1397/10/11

Registrant information

Name

Abbasali Dehgan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-08, 1397/10/18

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nebulized lidocaine 2% in patients sedation during awake intubation

Public title

The effect of nebulized lidocaine 2% in patients sedation during awake intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who candidates undergoing awake intubation

History of difficult intubations Patients over 14 years and below 70 years
Exclusion criteria:
Lack of cooperation (if the awake intubation is not essential) History of liver and kidney disease and coagulation Pathology of the respiratory tract Pregnancy Patients who have long received opioid or sedative medications Aspiration and regurgitation probability

Age

From **14 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **55**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

Golgasht Ave.

City

Tabriz

Province

West Azarbaijan

Postal code

5166614756

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.TBZMED.REC.1397.731

Health conditions studied

1

Description of health condition studied

Inhalation sedation

ICD-10 code

Y48.0

ICD-10 code description

Inhaled anaesthetics

Primary outcomes

1

Description

Depth of sedation

Timepoint

3 minutes after sedation with midazolam and 10 minutes after inhalation of lidocaine nebulizer 2%

Method of measurement

Bispectral (BIS) index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Nebulized lidocaine 2% with a dose of 3 mg/kg and 6 Lit/min flow rate for 10 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
 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
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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

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

Clinical Study Report

Yes - There is 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

Primary outcome

When the data will become available and for how long

Starting 6 month after publication

To whom data/document is available

All people

Under which criteria data/document could be used

Use is not allowed.

From where data/document is obtainable

Abbasali Dehghani

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

Send request via email

Comments