

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of inhalation and IV form of lidocaine on hemodynamic responses in patients undergoing Endotracheal intubation

Protocol summary

Summary

Single-blind randomized clinical trial study will done to evaluate the effect of inhaled and intravenous lidocaine on hemodynamic response in endotracheal intubation patient that hospitalized in ICU and between 25 to 40 years old in Arak Vali-Asr Hospital. Patients randomized to 3 groups (1, 2 intervention and control). The sample size was estimated for each group of 64 patient. In 1st intervention group 0.75 mg/kg lidocaine 4% will sprayed to the larynx and gloat, 2 minutes before intubation and the same dose will sprayed at intubation time. In 2th intervention group 0.75 mg/kg lidocaine 2% was injected intravenously, 2 minutes before intubation and the same dose will injected at intubation time. The main drugs used in the control group and of any type of lidocaine is not used. Inclusion criteria: patients between 25 to 40 years old admitted to the ICU and indication for endotracheal intubation; patients without underlying disease such as diabetes, hypertension, cardiovascular disease, kidney and liver diseases, respiratory diseases, recent respiratory infection; patients classified for 1 or 2 ASA; obtaining informed consent from attendant patients for the study. Exclusion criteria: patients who had a history of lidocaine hypersensitivity; pregnancy and lactation The systolic and diastolic blood pressure, mean arterial pressure and heart rate in the intervention groups 1 and 2 and the control group will determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080823552N1**

Registration date: **2015-09-29, 1394/07/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-29, 1394/07/07

Registrant information

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Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy Minister for Research and Technology Arak University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of inhalation and IV form of lidocaine on hemodynamic responses in patients undergoing Endotracheal intubation

Public title

Effect of different methods of administration of lidocaine on intubation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients between 25 to 40 years old admitted to the ICU and indication for endotracheal intubation; patients without underlying disease such as diabetes, hypertension, cardiovascular disease, kidney and liver diseases, respiratory diseases, recent respiratory infection; patients classified for 1 or 2 ASA; obtaining informed consent from attendant patients for the study. Exclusion criteria: patients who had a history of lidocaine hypersensitivity; pregnancy and lactation

Age

From **25 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **192**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Alamolhoda, Maskan, Arak

City

Arak

Postal code

Approval date

2014-11-26, 1393/09/05

Ethics committee reference number

793-171-7

Health conditions studied

1

Description of health condition studied

Hemodynamic changes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

systolic blood pressure

Timepoint

at intubation time and 2 and 5 minutes after Intubation

Method of measurement

mmhg with mercury sphygmomanometer

2

Description

diastolic blood pressure

Timepoint

at intubation time and 2 and 5 minutes after Intubation

Method of measurement

mmhg with mercury sphygmomanometer

3

Description

heart rate

Timepoint

at intubation time and 2 and 5 minutes after Intubation

Method of measurement

heart rate per minute

4

Description

mean arterial pressure

Timepoint

at intubation time and 2 and 5 minutes after Intubation

Method of measurement

mmhg with mercury sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

In 1th intervention group 0.75 mg/kg lidocaine 4% will sprayed to the larynx and gloat, 2 minutes before intubation and the same dose will sprayed at intubation time.

Category

Treatment - Drugs

2

Description

In 2th intervention group 0.75 mg/kg lidocaine 2% was injected intravenously, 2 minutes before intubation and the same dose will injected at intubation time.

Category

Treatment - Drugs

3

Description

The main drugs used in the control group and of any type of lidocaine is not used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak University of Medical sciences

Full name of responsible person

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rafiee

Street address

Arak, School of Medicine

City

Arak

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical sciences

Full name of responsible person

Dr. Abolfazl Jokar

Position

Emergency medicine specialist

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty