

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Investigating the effect of Lidocaine injection into tracheal lumen in order to prevent pulmonary infection in trauma patients under mechanical ventilation

Protocol summary

Study aim

Determining the effect of lidocaine injection in tracheal lumen on prevention of pulmonary infection in trauma patients under mechanical ventilation

Design

Randomized clinical trial with a control group, double-blind, randomized with rand (Excel) and randomized, with a sample size of 60 people.

Settings and conduct

In the intervention group, 1 mg per kilogram of body weight of 2% lidocaine without epinephrine will be injected into the tracheal lumen, 3 times a day for 72 hours, in the control group, the same amount of distilled water will be injected in the same period of time. On the morning of the fourth day, a sample of each patient's tracheal secretions will be sent to the laboratory for culture by an expert from the laboratory who is not aware of the intervention. The study is double-blinded (participants and Clinical caregiver).

Participants/Inclusion and exclusion criteria

Entry: being under mechanical ventilation for more than three days, not receiving broad-spectrum antibiotics (fluoroquinolones, 3rd and 4th generation cephalosporins, carbapenems, tazosin and other broad-spectrum antibiotics) within 72 hours before the intervention, consent of companions First degree for participating in the study Failure to enter: pulmonary disease (asthma, and COPD) and heart rhythm and rate disorders in the history taken from the patient's family

Intervention groups

Lidocaine without epinephrine will be injected into tracheal lumen of the patients of the intervention group for three days, and distilled water will be injected into the tracheal lumen of the patients of the control group during the same period. On the morning of the fourth day, samples of tracheal secretions will be taken from all the patients in order to compare the two groups in terms

of pulmonary infection.

Main outcome variables

Reduction of pulmonary infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201013049017N2**

Registration date: **2022-09-15, 1401/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-15, 1401/06/24**

Update count: **0**

Registration date

2022-09-15, 1401/06/24

Registrant information

Name

Hamid Talebzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3620 1995

Email address

talebzadeh.h@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-27, 1401/06/05

Expected recruitment end date

2022-10-29, 1401/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Lidocaine injection into tracheal lumen in order to prevent pulmonary infection in trauma patients under mechanical ventilation

Public title

Investigating the effect of Lidocaine injection into the airways in order to prevent lung infection

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Being under mechanical ventilation for more than three days
Consent of first-degree relative for participating in the study

Exclusion criteria:

Receiving broad-spectrum antibiotics (Fluoroquinolones, 3rd and 4th generation Cephalosporins, Carbapenems, Tazocin and other broad-spectrum antibiotics) within 72 hours before the intervention
Pulmonary disease (Asthma/COPD)
History of cardiac rhythm or rate disorders

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the limited randomization method of the Block randomization type according to gender and age. The size of all the blocks is equal and we will have 6 blocks in this two-group experiment (including 3 participants in the intervention group and 3 participants in the control group). The randomization tool is also used from the random sequence generation software, which in addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method. For concealment, we use random allocation concealment, which refers to the method used to perform a random sequence on the interventionists in the intensive care unit in this study, so that the allocated group is not known before the allocation of the individual. By using sealed opaque mail envelopes with a random sequence, in this method, each random sequence generated is recorded on a card, and the cards are placed in the mail envelopes in order and given to the anesthesiologist. In

order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the start time, based on the order of entry of qualified patients into the study, one of the letter envelopes will be opened in order and the assigned group of that participant will be revealed to the interventionist.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who is going to inject the drugs into the tracheal lumen won't be informed that if the substance is lidocaine or distilled water and the syringes containing the drug is prepared before. The laboratory expert also has no knowledge about which of the lung secretion samples is related to the control group and which is related to the intervention group. Patients' companions also do not know that lidocaine or distilled water will be given to their patient.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

ethics committee of Isfahan university of medical sciences

Street address

No. 11, Eshghi dead end, Baghe no alley, Mohtashame Kashani st.

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Isfahan

Province

Isfahan

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8175888113

Approval date

2022-04-25, 1401/02/05

Ethics committee reference number

IR.MUI.MED.REC.1401.031

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

Pulmonary infection

ICD-10 code

J15.9

ICD-10 code description

Unspecified bacterial pneumonia

Primary outcomes

1

Description

Pulmonary infection according to laboratory culture samples

Timepoint

before the start of the intervention and 72 hours after the start of the intervention

Method of measurement

Cultivation of pulmonary secretions in laboratory

Secondary outcomes

1

Description

Extubation time

Timepoint

After the end of the intervention (After 72 hours)

Method of measurement

Extubation date

2

Description

Time of discharge from ICU

Timepoint

After the end of the intervention (After 72 hours)

Method of measurement

Date of discharge from ICU

3

Description

Average CRP level

Timepoint

Before the intervention and 72 hours after the intervention

Method of measurement

CRP test

4

Description

Average ESR level

Timepoint

Before the intervention and 72 hours after the intervention

Method of measurement

ESR test

5

Description

Average Hemoglobin level (Hb)

Timepoint

Before the intervention and 72 hours after the intervention

Method of measurement

Complete blood count test results

6

Description

Average White blood cell level (WBC)

Timepoint

Before the intervention and 72 hours after the intervention

Method of measurement

Complete blood count test results

Intervention groups

1

Description

Intervention group: 1 mg per kilogram of body weight of 2% lidocaine without epinephrine will be injected into the tracheal lumen 3 times a day for 72 hours by the project manager. On the morning of the fourth day, a sample of each patient's tracheal secretions will be sent to the laboratory for culture.

Category

Treatment - Drugs

2

Description

Control group: 1 mg per kilogram of body weight of Distilled water will be injected into the tracheal lumen 3 times a day for 72 hours by the project manager. On the morning of the fourth day, a sample of each patient's tracheal secretions will be sent to the laboratory for culture.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospitah

Full name of responsible person

Parisa Karimian

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Sonbolestan alley, Ebnesina St

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Web page address

<http://amin.mui.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of Isfahan University of Medical Sciences

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Parisa Karimian

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hamid Talebzadeh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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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

Only information relevant to the main outcome can be published with de-identification of individuals and prior permission.

When the data will become available and for how long

The access period starts six months after the publication of the results

To whom data/document is available

All data will not be accessible and can only be accessed with the permission of patient's gaurdian for ethical authorities

Under which criteria data/document could be used

These data will be used for further studies about the antimicrobial effect of lidocaine

From where data/document is obtainable

Parisa Karimian(medical student) 0098 9136038372
karimian_p75@yahoo.com

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

The applicant must submit her/his request in the form of an e-mail and while fully introducing herself, she/he must also state the purpose of obtaining the data.

Comments