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

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Iran (Islamic Republic of)

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+98 31 3620 1995

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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.
City
Isfahan
Province
Isfehan
Postal code
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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Web page address
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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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NO 11, Eshghi dead end, Baghe no alley, Mohtasham Kashani St
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Web page address
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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
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Full name of responsible person
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Position
Assistant professor
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Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Medical student
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Other areas of specialty/work
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Email

Karimian_p75@yahoo.com

Web page address

https://med.mui.ac.ir/

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