Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of chlorhexidine mouthwash with irsha mouthwash drop on probable ventilator-associated pneumonia in intensive care unit

Protocol summary

Study aim

Comparison of the effect of Chlorhexidine mouthwash with Irsha Mouth–Wash Drop on probable ventilator-associated pneumonia in intensive care unit

Design

This study is a double-blind randomized clinical trial study with parallel groups. 80 intubated patients undergoing mechanical ventilation will be divided into two groups using Random Allocation Software. Intervention group 1 includes (washing of mouth and teeth with 10 cc chlorhexidine 0.2% three times of day until 5 days) and intervention group 2 (washing of mouth and teeth with 20-25 drops irsha 0.2% three times of day until 5 days).

Settings and conduct

This study was carried out in Al-Zahra hospital in Isfahan during 2019 to 2020. A total of 80 patients undergoing mechanical ventilation are enrolled in the study according to inclusion and exclusion criteria and are divided into two groups of chlorhexidine and irsha by random allocation software. Patients, drug prescriber, data collector, and data analyzer were not aware of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, requires mechanical ventilation for at least 48 hours, satisfaction to participate in the study and patients with natural teeth. Exclusion criteria: Specify any damage caused by endotracheal intubation, extubation before 5 days and patient death within 5 days of follow-up.

Intervention groups

Intervention group 1: Washing of mouth and teeth with 10 cc chlorhexidine 0.2% three times of day until 5 days. Intervention group 2: Washing of mouth and teeth with 20-25 drops irsha 0.2% three times of day until 5 days.

Main outcome variables

Incidence of pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150613022681N2**
Registration date: **2020-04-30, 1399/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-30, 1399/02/11**
Update count: **0**

Registration date

2020-04-30, 1399/02/11

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 195 1374

Email address

alikiaiib@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of chlorhexidine mouthwash with irsha mouthwash drop on probable ventilator-associated pneumonia in intensive care unit

Public title
Comparison of the effect of chlorhexidine mouthwash and irsha mouthwash drop in the prevention of pulmonary infection in hospitalized patients in the intensive care unit

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Requires mechanical ventilation for at least 48 hours Satisfaction to participate in the study Patients with natural teeth

Exclusion criteria:
Specify any damage caused by endotracheal intubation. Extubation before 5 days Patient death within 5 days of follow-up

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 80 intubated patients in intensive care unit are enrolled in the study according to inclusion and exclusion criteria and are divided into two groups with blocking method and by Random Allocation Software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are blinded by the type of medication used in the intensive care unit due to their intubation and relaxation, the drugs are also prepared in separate containers with numbers, and the nurse who used the medication for the patients does not know the type of drugs. After collecting the information, it enters the software by numbering, and after performing statistical analysis and completion of the work, the codes are determined.

Placebo
Not 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
Hezar Jerib Street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2019-11-12, 1398/08/21

Ethics committee reference number
IR.MUI.MED.REC.1398.414

Health conditions studied

1

Description of health condition studied
Ventilator associated pneumonia

ICD-10 code
J95.851

ICD-10 code description
Ventilator associated pneumonia

Primary outcomes

1

Description
Ventilator associated pneumonia incidence

Timepoint
After using the drug on a daily basis up to 5 days

Method of measurement
Clinical pulmonary infection score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: washing of mouth and teeths with 10 cc chlorhexidine 0.2% three times of day until 5 days.

Category
Prevention

2

Description
Intervention group: washing of mouth and teeths with 20-25 drops irsha 0.2% three times of day until 5 days.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Babak Alikiai
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Shohadaye Sofe St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayesh Haghjoo
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Web page address
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
Babak Alikiai
Position
Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Position
Assistant Professor

Latest degree
Medical doctor

Other areas of specialty/work
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Information belongs to government agency

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Because the information belongs to a government agency, it cannot be shared.

When the data will become available and for how long
Any time

To whom data/document is available
Any person

Under which criteria data/document could be used
Under any circumstances

From where data/document is obtainable
Any person, any time

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

Comments