

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of Chlorhexidine mouthwash with Dine mouthwash on prevention of ventilator-associated pneumonia in pediatric intensive care unit

Protocol summary

Study aim

The aim of this study is comparing the effect of chlorhexidine mouthwash with Dine mouthwash on prevention of ventilator-associated pneumonia in patients in PICU

Design

Clinical trial , phase 2 , double blinded, 80 patients between 2 months and 14 years old, admitted in PICU , randomized in two groups of Dine or Chlorhexidin mouthwash recipients

Settings and conduct

This is a double blinded study on 80 patients admitted in PICU of Emam Hosein hospital of Esfahan , who receive Dine or Chlorhexidin mouthwash and will be compared about incidence of pneumonia

Participants/Inclusion and exclusion criteria

Patients with age of 2 months to 14 years Patients who need mechanical ventilation for at least 48 hours Admission in pediatric intensive care unit No Intubation before admission in PICU No Oral or perioral lesions No Immune deficiency No Admission with causes of infectious or respiratory diseases No Use of antibiotics before admission No Sensitivity to herbal medication in past medical history

Intervention groups

Patients who receive Dine or Chlorhexidin mouthwash

Main outcome variables

Incidence of pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180520039739N2**

Registration date: **2018-11-26, 1397/09/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-26, 1397/09/05**

Update count: **0**

Registration date

2018-11-26, 1397/09/05

Registrant information

Name

Mohammadreza Habibzadeh siahroodkolaee

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Chlorhexidine mouthwash with Dine mouthwash on prevention of ventilator-associated pneumonia in pediatric intensive care unit

Public title

Evaluation of effect of chlorhexidine on prevention of ventilator associated pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with age of 2 months to 14 years
Patients who need mechanical ventilation for at least 48 hours
Admission in pediatric intensive care unit

Exclusion criteria:

Intubation before admission in PICU
Oral or perioral lesions
Immune deficiency
Admission with causes of infectious or respiratory diseases
Use of antibiotics before admission
Sensitivity to herbal medication in past medical history

Age

From **2 months** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization(random number table) : even numbers for Chlorhexidin and odds for Dine groups

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and their nurses are not aware of the kind of mouthwash and executor of plan will give the mouthwash to the nurses.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan university of medical sciences

Street address

Esfahan university of medical sciences , Hezarjerib Ave.

City

Esfahan

Province

Isfahan

Postal code

ندارد

Approval date

2017-04-25, 1396/02/05

Ethics committee reference number

IR.MUI.REC.1396.30975

Health conditions studied

1

Description of health condition studied

Ventilator associated pneumonia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incidence of pneumonia

Timepoint

In 5 days

Method of measurement

Infectious Diseases Society of America Guidelines and American Thoracic Society guidelines

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: treatment with 10 cc of 0.2% chlorhexidine gluconate mouthwash (Emad darou company) 3 times per day for 5 days

Category

Treatment - Drugs

2

Description

Intervention group: treatment with 20 drop of dine mouthwash (Dineh Iran) 3 times per day for 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hosein hospital

Full name of responsible person

Mohammadreza Habibzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
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research@mui.ac.ir
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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