Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

the effects of oral rise with 0/2 and 2% chlorhexidine on oropharyngeal colonization and ventilator associated pneumonia in adult intensive care units

Protocol summary

Summary

objective : comparison of oral rinse with chlorhexidine 0/2 and 2 % on the oropharyngeal colonization and ventilator associated pneumonia in adult intensive care units. design: randomized clinical trial, double blind. method: 112 adult patients ,age of 18 years and older that had inclusion criteria randomly assigned in two groups, chlorhexidine 0/2 % group which receive oral care protocol with chlorhexidine 0/2% and chlorhexidine 2% group which receive oral care protocol with chlorhexidine 2%.Before oral care initiation, oral assessment is done and cultures from oropharyngeal and tracheal is obtained and sent to laboratory. Patients followed and ventilator associated pneumonia is checked daily until Patients are intubated or they are transferred to ICU or discharged ,or they are diagnosed as pneumonia, or died in 28 days. 4) Study samples are Patients admitted to Nemazee and Rajaee hospitals ICUs who are intubated and mechanically ventilates for at least 48 hours. Inclusion and exclusion criteria: main inclusion criteria were : age 18 years and older, intubated and mechanical ventilated within 48 hours of admission. main exclusion criteria were: a clinical diagnosis of pneumonia at the time of admission, readmission to the ICU. 5) interventions: oral care protocol with chlorhexidine 0/2% in chlorhexidine 0/2% group and same oral care protocol with chlorhexidine 2% in chlorhexidine 2% group, examination for pneumonia daily and sending oropharyngeal and tracheal cultures on admission and when patients are extubated or transferred or discharged or diagnosed pneumonia or died in 28 days. 6) main outcomes, the rate of ventilator associated pneumonia and oropharyngel colonization. Variables : radiologic, clinical and laboratory findings.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100624382N1**
Registration date: **2015-11-26, 1394/09/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-26, 1394/09/05

Registrant information

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Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-05, 1394/01/16

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
the effects of oral rise with 0/2 and 2% chlorhexidine on oropharyngeal colonization and ventilator associated pneumonia in adult intensive care units

Public title
the effects of oral rise with 0/2 and 2% chlorhexidine on oropharyngeal colonization and ventilator associated pneumonia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: 18 years and older; informed consent; patients intubated and who on mechanical ventilation within 48 hours of admission; without a clinical diagnosis of pneumonia at the time of admission ; not to be pregnant ; without significant oral, facial trauma; not to readmitted to the ICU ; without known hypersensitivity to chlorhexidine; without an immunosuppression (disease or drug induced, e.g. organ transplant patient or those on long term steroid therapy); not to hospitalized for burn injury. Exclusion criteria: aspiration; a diagnosed thrombocytopenia (platelet less than 40000); INR above 2 or other coagulopathy.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Zand Street, Shiraz

City
Shiraz

Postal code
7134814336

Approval date
2015-02-08, 1393/11/19

Ethics committee reference number
93-7363

Health conditions studied

1

Description of health condition studied
ventilator associated pneumonia

ICD-10 code
J20-J22

ICD-10 code description
other acute lower respiratory infections

Primary outcomes

1

Description
oropharyngeal colonization

Timepoint
before intervention and if had exclusion criteria

Method of measurement
send culture and report semiquantitative

Secondary outcomes

1

Description
ventilator associated pneumonia

Timepoint
before, during and until 48hours and if had exclusion criteria

Method of measurement
clinical pulmonary infection score and clinical diagnose and start new antibiotic by intensivist

Intervention groups

1

Description
In control group, oral care protocol include, suction, oral assessment, brushing and rubbing saturated oral foam application of chlorhexidine 0/2% 10ml on gum, mucosa, teeth, hard palate, every 12 hours is done.

Category
Prevention

2

Description
In intervention group, oral care protocol include, suction, oral assessment, brushing and rubbing saturated oral

foam application of chlorhexidine 2% 10ml on gum, mucosa, teeth, hard palate, every 12 hours is done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nemazee Hospital

Full name of responsible person

Leila Zahed

Street address

Nemazee Square, Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Rajaee Hospital

Full name of responsible person

Leila Zahed

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Chamran Blvd. , Shiraz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shiraz University of Medical Science

Full name of responsible person

Seyed Basir Hashemi

Street address

Zand Street, Shiraz

City

Shiraz

Grant name

93/451495

Grant code / Reference number

93-7363

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Shiraz University of Medical Science

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

Shiraz University of Medical Sciences-Fatemeh (PBUH) School of Nursing & Midwifery

Full name of responsible person

Leila Zahed

Position

MS(intensive care) Student

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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