

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

A comparative study of chlorhexidine mouthwash with plant-based mouthwash in the prevention of ventilator-related pneumonia in patients admitted to the intensive care unit

Protocol summary

Study aim

Determining and comparing the effect of chlorhexidine mouthwash with plant-based mouthwash in the prevention of ventilator-related pneumonia in patients admitted to the intensive care unit of Al-Zahra Hospital in 2018-2019

Design

A clinical trial with two intervention groups, with parallel, two-way blind, randomized groups

Settings and conduct

This study was a randomized double-blind clinical trial that was performed in 1397 in the intensive care unit of Al-Zahra Hospital in Isfahan. 80 patients admitted to the intensive care unit were selected to participate in this study if they had entry criteria. In order to observe blindness, the study of patients and the individual who determines the final result of the study (the patient's physician) was not aware of the groups under study and the study was of the double-blind type.

Participants/Inclusion and exclusion criteria

inclusion criteria: age over 18 years, no chip use before entering the intensive care unit

Intervention groups

In the first group, treatment with chlorhexidine is performed. Chlorhexidine gluconate 0.2% of the Shahrदारou-Tehran Pharmaceutical Factory is used for these patients. In the second group, treatment was started with Dineh mouthwash made by Dineh Pharmaceutical Company. Frequency, timing, and method of mouth washing in both groups will be done in the same way and three times a day for 5 days, every eight hours. Was.

Main outcome variables

Duration of hospitalization in the ICU, Pneumonia, Oral infections, Chronic obstructive pulmonary disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200413047059N1**

Registration date: **2020-11-09, 1399/08/19**

Registration timing: **retrospective**

Last update: **2020-11-09, 1399/08/19**

Update count: **0**

Registration date

2020-11-09, 1399/08/19

Registrant information

Name

Yeganeh Fatemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5550 0111

Email address

ygn.ftm1994@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of chlorhexidine mouthwash with plant-based mouthwash in the prevention of ventilator-related pneumonia in patients admitted to the intensive care unit

Public title

Comparative effect of chlorhexidine mouthwash with plant-based mouthwash in the prevention of pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Requires mechanical ventilation for at least 48 hours Do not use the chip pipe before entering the intensive care unit No specific lesions in and around the mouth Lack of safety defects Do not take antibiotics before hospitalization No pregnancy Lack of allergy to plant compounds Has natural teeth Free and informed written consent of the patient's companion or guardian to participate in the study

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simply put, the individual was divided into two groups of 40 by referring to the hospital and the relevant department and using the SPSS statistical software version 23.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to observe blindness, the study of patients and the person who determines the final result of the study (the patient's doctor) will not be aware of the groups under study and the study will be of the blind type.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee for Ethics in Biomedical Research

Street address

Hezar Jarib St. Isfahan University of Medical Sciences and Health Services

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2020-04-07, 1399/01/19

Ethics committee reference number

IR.MUI.MED.REC.1399.021

Health conditions studied

1

Description of health condition studied

Ventilate-related pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes

1

Description

Ventilator-related pneumonia

Timepoint

At the beginning of the study and 3 weeks after using two mouthwashes

Method of measurement

A microbial infection of the lung that occurs more than 48 hours after mechanical ventilation with a ventilator. Diagnosis of this type of pneumonia is based on the symptoms of pulmonary infection (including: purulent discharge, fever and leukocytosis), bacteriological evidence of pulmonary infection, and evidence of lung infection on specific radiographic images.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, treatment with chlorhexidine is 0.2%. The frequency, timing, and manner of mouth washing in this group will be performed in the same way, three times a day for 5 days, every eight hours. First, a sterile gauze wrap is wrapped around an abscess and

then soaked in a mouthwash, and like a toothbrush, all areas of the mouth, gums, tongue, throat, and teeth are washed for 6 minutes. The amount of chlorination in each wash is 10 cc and in the case of butter, the consumption of 25-20 drops per half cup of water is dissolved.

Category

Treatment - Drugs

2**Description**

Intervention group: Dine mouthwash made by Dineh Pharmaceutical Company. In the second group, treatment will begin with a mouthwash. Frequency, timing, and method of mouth washing in both groups will be done in the same way and three times a day for 5 days, every eight hours. First, a sterile gauze wrapped around a tongue blade and then soaked in mouthwash, and like a toothbrush, all areas of the mouth, gums, tongue, throat, and teeth are washed for 6 minutes. The amount of chlorination in each wash is 10 cc and in the case of butter, the consumption of 25-20 drops per half cup of water is dissolved.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital's intensive care unit in Isfahan

Full name of responsible person

Babak Alikiaii

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Hezar Jarib St.-Isfahan University of Medical Sciences and Health Services

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Babak Alikiaii

Street 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

Yeganeh Fatemi

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

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

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

Title and more details about the data/document

A part of the data such as information about the main consequence

When the data will become available and for how long

Starting access in the fall of 2020

To whom data/document is available

Researchers

Under which criteria data/document could be used

In case of further studies and changes in different doses and materials, the use of documents is allowed.

From where data/document is obtainable

Submit a request by e-mail to the author and provide a title related to the study

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

The request will be sent by e-mail and the documents will be sent one week after the review.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Babak Alikiaii

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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