

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of two brushing methods with Chlorhexidine mouthwash and Matricaria (Chamomile) mouthwash on ventilator-induced pneumonia (VAP) in patients admitted to intensive care unit

Protocol summary

Study aim

Determining the effect of two methods of brushing with chlorhexidine mouthwash and matrix mouthwash on the incidence of ventilator-induced pneumonia (VAP) in hospitalized patients in the intensive care unit

Design

A three-arm, parallel-group, triple-blinded randomized clinical trial with a control group

Settings and conduct

Eighty eligible patients admitted to the traumatic intensive care unit of Imam Reza Hospital and Valiasr in 2020 selected by convenience sampling method and allocated to one control and two intervention groups Simple randomization. All patients were examined for oral mucosal lesions and dental plaque before intervention and on the 2nd and 5th days after intervention. The study is triple-blinded where the patients, care-providers, and data analysts are not aware of the intervention. Patients in spine position, and if applicable, the head in a 30-degree gradient and the face in a lateral direction. The mouth, gums, tongue, pharynx, and teeth are brushed with a soft brush before intervention. Mouthwashes applied on a daily basis, every 12 hours, for 5 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent provided by the patient or guardian for participation Age between 15 and 65 years Less than 6 hours passed from the patient's admission in the intensive care unit Having an oral tube Having at least 12 natural teeth and not having more than 6 dentures.Exclusion criteria:Diabetes Immune system disorders Traumatic oral injuries Taking anti-coagulant drugs

Intervention groups

There are tow 40-member groups. In the control group, 0.2 percent chlorhexidine gluconate mouthwash will be used. In the intervention group, Matricaria chymomilla

extract at a concentration of 10 percent used.

Main outcome variables

Incidence of pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190530043773N2**

Registration date: **2020-09-08, 1399/06/18**

Registration timing: **retrospective**

Last update: **2020-09-08, 1399/06/18**

Update count: **0**

Registration date

2020-09-08, 1399/06/18

Registrant information

Name

rasool solaimani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3242 4948

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two brushing methods with Chlorhexidine mouthwash and Matricaria (Chamomile) mouthwash on ventilator-induced pneumonia (VAP) in patients admitted to intensive care unit

Public title

Comparison of the effect of two methods of brushing with chlorhexidine and Matrica (Chamomile) mouthwash on the incidence of Ventilator-Associated Pneumonia (VAP)

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient or guardian consent Severe oral and maxillofacial injury Endotracheal tube Not taking antibiotics before and during hospitalization Lack of immune system disorder Lack of ulcers, infection and oral trauma

Exclusion criteria:

Diabetes Immune system disorders Traumatic oral injuries Taking anti-coagulant drugs

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients who met the inclusion criteria were selected by convenience sampling method and randomly assigned to one of the two intervention groups A (chamomile) and group B (chlorhexidine). The card number was marked with the letters A and B and was written on card A of the chamomile intervention group and on card B of the control group of chlorhexidine. The researcher was asked to remove one of the cards, without knowing which group the patient was in, so the samples were divided into two groups to complete the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and outcome assessors were not informed about how to participate in the blinding process

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zabol University of Medical Sciences

Street address

Zabol, Shahid Rajaei St., Vice Chancellor of Zabul University of Medical Sciences

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Approval date

2019-06-24, 1398/04/03

Ethics committee reference number

IR.ZBMU.REC.1398.095

Health conditions studied**1****Description of health condition studied**

Pneumonia

ICD-10 code

J17

ICD-10 code description

Pneumonia in diseases classified elsewhere

Primary outcomes**1****Description**

Ventilator Associated Pneumonia(VAP)

Timepoint

Pneumonia on the fifth day after the intervention

Method of measurement

Questionnaire score CPIS(Clinical Pulmonary Infection Score)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group (Matricaria chamomilla): Matricaria

chamomilla extract at a concentration of 10 percent (made by Adonis Gol Darou Company) administered three times daily with a volume of 10 milliliters for 5 days.

Category

Prevention

2

Description

Control group: (Chlorhexidine gluconate): The control group patients used 0.2 percent chlorhexidine gluconate mouthwash three times daily with a volume of 10 milliliters for 5 days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Valiasr Hospital

Full name of responsible person

RasoolSolaimaniMighadam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Zabol 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

Zabol University of Medical Sciences

Full name of responsible person

Rasool Soleimani Moghaddam

Position

University student

Latest degree

Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

No - There is not 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

The total potential data can be shared after unidentifying people

When the data will become available and for how long

9 months after publishing the results

To whom data/document is available

Study data will only be available to researchers working in universities and academic institutions

Under which criteria data/document could be used

Only tests performed on study data

From where data/document is obtainable

To receive the data, they can only send their application to the email address of the person responsible for the study. rasool.solaimani@yahoo.com

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

After reviewing the code of ethics of the requesting inquiry committee and the approval date and the applicant's university identification document

Comments