

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparing the efficacy of *Matricaria chamomilla*, *Achillea millefolium*, and chlorhexidine gluconate mouthwashes on dental plaque and oral mucosal lesions of patients using ventilator in the intensive care unit

Protocol summary

Study aim

To compare the efficacy of *Matricaria chamomilla*, *Achillea millefolium*, and chlorhexidine gluconate mouthwashes on dental plaque and oral mucosal lesions of patients using ventilator

Design

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

Settings and conduct

Seventy-five eligible patients admitted to the traumatic intensive care unit of Imam Reza Hospital of Birjand in 2019 will be selected by convenience sampling method and allocated to one control and two intervention groups via permuted block randomization. All patients will be 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 will be in spine position, and if applicable, the head will be 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 will be applied on a daily basis, every 8 hours, for 5 days.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: Informed consent provided by the patient or guardian; age between 15 and 65 years; and having an oral tube. Major exclusion criteria: Diabetes and traumatic oral injuries.

Intervention groups

There are three 25-member groups. In the control group, 0.2 percent chlorhexidine gluconate mouthwash will be used. In the first intervention group, *Matricaria chymomilla* extract at a concentration of 10 percent, and in the second intervention group, *Achillea millefolium* extract at a concentration of 5% will be used.

Main outcome variables

Oral lesions, dental plaque

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190714044197N1**

Registration date: **2019-08-04, 1398/05/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-04, 1398/05/13**

Update count: **0**

Registration date

2019-08-04, 1398/05/13

Registrant information

Name

Fatemah Sabzehkar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 56 3245 4252

Email address

fsabzehkar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Matricaria chamomilla, Achillea millefolium, and chlorhexidine gluconate mouthwashes on dental plaque and oral mucosal lesions of patients using ventilator in the intensive care unit

Public title

The effect of different mouthwashes on oral hygiene of patients using ventilator

Purpose

Prevention

Inclusion/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

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be recruited via convenience sampling method and allocated to study groups via permuted block randomization.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, patients and their companions will be aware of the overall study design but will not be aware of the type of intervention the patient is to receive. Mouthwash solutions will be delivered to the nurses participating in the study in similar containers labeled A, B, or C, and the nurses will not be aware of the solution in the containers. Moreover, the statistical analyzer will not be informed of the interventions.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari Street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2019-07-09, 1398/04/18

Ethics committee reference number

IR.BUMS.REC.1398.125

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

oral mucosal lesions

ICD-10 code

K13.70

ICD-10 code description

Unspecified lesions of oral mucosa

2**Description of health condition studied**

dental plaque

ICD-10 code

K02.9

ICD-10 code description

Dental caries, unspecified

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

Oral mucosal lesions

Timepoint

Before the intervention, the second and fifth days after the intervention

Method of measurement

Beck Oral Assessment Scale

2**Description**

Dental plaque

Timepoint

Before the intervention, the second and fifth days after the intervention

Method of measurement

Mucosal-plaque score index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (*Matricaria chamomilla*): *Matricaria chamomilla* extract at a concentration of 10 percent (made by Adonis Gol Darou Company) will be administered three times daily with a volume of 10 milliliters for 5 days.

Category

Prevention

2

Description

Intervention group 2 (*Achillea millefolium*): *Achillea millefolium* extract at a concentration of 5 percent (made by Adonis Gol Darou Company) will be administered three times daily with a volume of 10 milliliters for 5 days.

Category

Prevention

3

Description

Control group (Chlorhexidine gluconate): The control group patients will use 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

The intensive Care Unit of Imam Reza Hospital

Full name of responsible person

Fatemeh Sabzehkar

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Taleghani Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

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9717853577

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drkazemi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Fatemeh Sabzeh Kar

Position

Clinical supervisor

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Marzieh Mogharab
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set

When the data will become available and for how long

after the paper extracted from the research project is published and for six months

To whom data/document is available

paper readers

Under which criteria data/document could be used

for research purposes

From where data/document is obtainable

personal correspondence with the corresponding author of the paper

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

email

Comments