# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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)

**Phone**
+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

**Street address**

Taleghani Ave.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717936643

**Phone**

+98 56 3245 4252

**Email**

fsabzehkar@bums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr. Tooba Kazemi

**Street address**

Ghaffari St

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5632

**Email**

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

**Street address**

Ghafari St

**City**

Birjand

**Province**

South Khorasan

**Postal code**
9717936643
**Phone**
+98 56 3245 4252
**Email**
fsabzehkar@bums.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Marzieh Mogharab
**Position**
Instructor
**Latest degree**
Master
**Other areas of specialty/work**
Nursery
**Street address**
Ghafari St.
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717853577
**Phone**
+98 56 3239 5632
**Email**
marziehmogharab@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Fatemeh Sabzehkar
**Position**
Clinical supervisor
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
**Street address**
Taleghani Ave.
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717936643
**Phone**
+98 56 3245 4252
**Email**
fsabzehkar@bums.ac.ir

## 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**