

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Investigating the effect of mouthwash containing an acidophilic strain of *Lactobacillus brevis* enriched with selenium on the microbial flora of the gastrointestinal tract and the healing of oral ulcers in ICU patients

Protocol summary

Study aim

Investigating the effect of mouthwash containing an acidophilic strain of *Lactobacillus brevis* enriched with selenium on the microbial flora of the gastrointestinal tract and the healing of oral ulcers in ICU patients of Shahid Bahonar Medical Center, Kerman.

Design

The number of patients studied in this project (sample size) will be at least sixty people who will be divided into three equal groups of twenty people (1. normal saline 0.9%, 2. chlorhexidine 0.12%, and 3. bacterial suspension enriched in normal solution Saline 0.9%) This study is an interventional or clinical trial type and is conducted in a double blind method

Settings and conduct

This study is an interventional or clinical trial type and is conducted by double blind method (patient and caregiver and clinical outcome assessor) in the ICU department of Shahid Bahonar Medical Center in Kerman.

Participants/Inclusion and exclusion criteria

The criteria for entering the study are being hospitalized in the ICU department of Bahonar Hospital, not having sepsis, pneumonia or other active infection, and not having a known immunodeficiency. Also, according to the effect of obesity (body mass) and nutritional status of the patient (such as gavage tolerance) in the healing process of the wound, as well as the location of the wound, patients are matched (for intubated patients, cases where the intubation tube is cuffed are selected).

Intervention groups

The studied mouthwash group Chlorhexidine mouthwash group Normal saline mouthwash group (control)

Main outcome variables

Oral ulcer, digestive tract flora

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221221056887N1**

Registration date: **2023-03-06, 1401/12/15**

Registration timing: **prospective**

Last update: **2023-03-06, 1401/12/15**

Update count: **0**

Registration date

2023-03-06, 1401/12/15

Registrant information

Name

Farshid Ataollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 8942

Email address

farshid.ataollahi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of mouthwash containing an acidophilic strain of *Lactobacillus brevis* enriched with selenium on the microbial flora of the gastrointestinal tract and the healing of oral ulcers in ICU patients

Public title

Investigating the effect of mouthwash containing an acidophilic strain of *Lactobacillus brevis* enriched with selenium on the microbial flora of the gastrointestinal tract and the healing of oral ulcers in ICU patients of Shahid Bahonar Medical Center, Kerman.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being hospitalized in the ICU department of Bahonar Hospital No sepsis, pneumonia, or other active infection No known immunodeficiency For intubated patients, cases that the intubation tube is cuffed are selected

Exclusion criteria:

The patient was discharged from the ICU and anesthesia service of Bahonar Hospital

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After examining the patients in terms of the criteria for entering the study and obtaining informed consent, the total number of people with conditions for entering the study will be divided into two equal groups, and the placement of people in these two groups will be in the form of block randomization with the blinding process (in If the total sample size is not available for block randomization at the beginning of the study, randomization using random number table method is used.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study has been double-blind, so that the patient, the clinical caregiver, the evaluator, and the outcome researcher do not know the type of mouthwash prescribed, and it is only prescribed based on mouthwash number 1, 2, and 3.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Jahad Blvd. Ebn Sina Avenue, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.KMU.REC.1401.529

Health conditions studied

1

Description of health condition studied

oral ulcer

ICD-10 code

K12.1

ICD-10 code description

Other forms of stomatitis

2

Description of health condition studied

Changing the flora of the digestive tract

ICD-10 code

A09

ICD-10 code description

Infectious gastroenteritis and colitis, unspecified

Primary outcomes

1

Description

Oral ulcer

Timepoint

The entire duration of drug administration

Method of measurement

Observation and examination of the wound by the researcher(wound healing time AND Wound dimensions)

2

Description

Gastrointestinal flora

Timepoint
The beginning and the end of the study and according to the routine of the department

Method of measurement
The information available in the system and the response section of the patient's tests (Microbial flora of the pharynx)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The studied mouthwash (produced in Kerman University of Medical Sciences, Iran, where Lactobacillus isolated from dairy and edible products is cultured in an environment containing selenium salt to be enriched with selenium, and after laboratory approval of the bacteria for human use daily 4 50 cc of normal saline 0.9% containing 109 cfu of this probiotic for 30 seconds is prescribed for patients as a mouthwash for one week.

Category

Treatment - Drugs

2

Description

Intervention group: Chlorhexidine mouthwash (manufactured by Vi One-Iran, which is diluted to a concentration of 0.12% and then 50 cc of this mouthwash is prescribed to the patients 4 times a day for 30 seconds for a week)

Category

Treatment - Drugs

3

Description

Control group: normal saline 0.9% (manufactured by Iran-Iran company, which is used at a concentration of 0.9% and 50cc of this mouthwash is prescribed to patients 4 times a day for 30 seconds for a week)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar hospital

Full name of responsible person

Farshid Ataollahi

Street address

Qorani St. - Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

bahonarhospital@kmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

Street address

Ebn-e-Sina St.,Jahad Blvd.,

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3719

Email

kmu@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Biotechnology Development Headquarters

Full name of responsible person

Ruhollah Dehghani Firouzabadi

Street address

scientific and technological department of presidential office, No., 20, Ladan alley, North Sheikh

Bahayee St., MollaSadra St., Vanak Sq.

City

Tehran

Province

Tehran

Postal code

1991745681

Phone

+98 24 83539

Email

pr@isti.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Biotechnology Development Headquarters

Proportion provided by this source

50

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Farshid Ataollahi

Position

Non-faculty general practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Qaraney St, Next to Shahid Bahonar Hospital, Upper Floor Of Pharmacy No.2 , Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616911319

Phone

+98 34 3223 8942

Fax

+98 34 3223 8942

Email

farshid.ataollahi@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Farshid Ataollahi

Position

Non-faculty general practitioner

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Farshid Ataollahi

Position

Non-faculty general practitioner

Latest degree

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Other areas of specialty/work

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Fax

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Email

farshid.ataollahi@gmail.com

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

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

Project data will be published without mentioning personal information and identification of study subjects

When the data will become available and for how long

Access starts from the publication of the final report

To whom data/document is available

The data that can be published is published in the form of a final report and is available to everyone

Under which criteria data/document could be used

The data that can be published will be announced in the final report of the plan

From where data/document is obtainable

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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

After the completion of the project (1 year)

Comments