

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of Lactobacillus salivarius NK 02 probiotic mouthwash on mild to moderate chronic periodontitis

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effect of mouthwash containing probiotic Lactobacillus salivarius NK02 on mild to moderate chronic periodontitis.

##### Design

thriple blind clinical trial , Control group with factorial and randomized groups by random allocation rule , 42 patients with mild to moderate chronic periodontitis

##### Settings and conduct

Patients will be examined first and if they have mild to moderate chronic periodontitis they will receive written consent. Patients are then fully scaling and braced. After that mouthwash is administered. 10 ml of the mouthwash is used twice daily for 1 minute 30 minutes after brushing for up to 1 month. All patients should be referred for re-examination and treatment results.

##### Participants/Inclusion and exclusion criteria

42 patients were selected from patients diagnosed with mild to moderate chronic periodontitis using radiologic and clinical findings. Written consent was obtained from patients.

##### Intervention groups

Probiotic mouthwash. Chlorhexidine mouthwash. Placebo mouth wash (normal saline). control

##### Main outcome variables

Modified Gingival Index (MGI) bleeding on probing (BOP)  
Probing depth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191002044957N1**  
Registration date: **2020-02-11, 1398/11/22**  
Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-11, 1398/11/22**

Update count: **0**

##### Registration date

2020-02-11, 1398/11/22

##### Registrant information

###### Name

Faezeh Akbari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3867 2772

###### Email address

faezeakbari1375555@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-02-19, 1398/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Lactobacillus salivarius NK 02 probiotic mouthwash on mild to moderate chronic periodontitis

##### Public title

Effect of probiotic mouthwash on chronic periodontitis

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Patients Referred to Periodontics Department of Zahedan Dental School, with Mild to Moderate Chronic

Periodontitis The presence of envelopes between 3 and 7 mm Patient satisfaction Full public health The presence of at least 20 teeth in the mouth Lack of systemic disease (lactose intolerance, immunodeficiency disease, etc.) Lack of dry mouth Not taking any medication that affects the amount and quality of saliva No antibiotic use in the last 3 months No use of immunosuppressants in the past 6 months No smoking and other tobacco products Absence of pregnancy and lactation Non-use of other probiotic products Non-receive periodontal treatment in the last 6 months

**Exclusion criteria:**

Participant's unwillingness to continue treatment

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Forty-four patients were randomly divided into three groups (n = 14).

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Probiotic mouthwashes, chlorhexidine and normal saline mouthwashes are packaged in similar containers and labeled and coded in groups (A), (B) and (C). The codes for each container are unknown to the patient, therapist (student) and analyzer and will be kept confidential until the end of the study by the supervisor. Patients were randomly divided into three groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Zahedan University of Medical Sciences

**Street address**

Dr. Hasabi Square, Zahedan University of Medical

Sciences

**City**

zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2019-09-29, 1398/07/07

**Ethics committee reference number**

IR.ZAUMS.REC.1398.371

**Health conditions studied**

**1**

**Description of health condition studied**

Chronic periodontitis

**ICD-10 code**

K05.3

**ICD-10 code description**

Chronic periodontitis

**Primary outcomes**

**1**

**Description**

Probing Depth

**Timepoint**

Immediately before us of mouthwash / one month later / three months later

**Method of measurement**

Measured by Williams probe

**2**

**Description**

Modified Gingival Index

**Timepoint**

Immediately before us of mouthwash / one month later / three months later

**Method of measurement**

Measurement by clinical examination

**3**

**Description**

Bleeding On Probing

**Timepoint**

Immediately before us of mouthwash / one month later / three months later

**Method of measurement**

Clinical observation of post-probing bleeding by Williams probe

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Control group: 10 ml of placebo mouthwash(Normal Saline) is used twice a day for 1 minute, 30 minutes after brushing for up to 1 month.

#### Category

Placebo

### 2

#### Description

Intervention group: 10 ml of probiotic mouthwash is used twice a day for 1 minute, 30 minutes after brushing for up to 1 month.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: 10 ml of Chlorhexidine mouthwash is used twice a day for 1 minute, 30 minutes after brushing for up to 1 month.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Zahedan Dental School Periodontology Section

##### Full name of responsible person

Faezeh Akbari

##### Street address

Azadegan Shargi St.

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9817699693

##### Phone

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##### Fax

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##### Email

Arbabi.Parvin@zaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Deputy of Research and Technology of Zahedan University of Medical Sciences

##### Full name of responsible person

Dr Nor Mohammad Bakhshani

##### Street address

Azadegan Shargi St.

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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

Deputy of Research and Technology of Zahedan 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

Zahedan University of Medical Sciences

##### Full name of responsible person

Sanaz Isar

##### Position

B.Sc., Research Expert

##### Latest degree

Bachelor

##### Other areas of specialty/work

Library and Medical Information

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Parvin Arbabi Kalati

**Position**

متخصص جراحی لثه

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Faezeh Akbari

**Position**

Dentistry student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be 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