

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)

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+98 51 3867 2772

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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

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Azadegan Shargi St.

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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

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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