

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effects of the probiotics suspension containing lactobacillus salivarius on gingivitis

Protocol summary

Study aim

The effect of Lactobacillus salivarius probiotic suspension on the plaque index (PI) of patients with gingivitis The effect of Lactobacillus salivarius probiotic suspension on gingival index (GI) in patients with gingivitis -The effect of Lactobacillus salivarius probiotic suspension on bleeding on probing (BOP) in patients with gingivitis The effect of Lactobacillus salivarius probiotic suspension on oral hygiene index (OHI) in patients with gingivitis

Design

Randomized, triple blinded clinical trial with a parallel group design of 42 patients.

Settings and conduct

This study will be carried out in the periodontology department of the Faculty of Dentistry of Mazandaran University of Medical Sciences. It is a triple blinded study(partients, analysor and researcher)

Participants/Inclusion and exclusion criteria

Inclusion criteria are plaque induced gingivitis($GI \geq 1$) and presence of 20 teeth(5 teeth in each quadrant).
Exclusion criteria are $PD > 3$, pregnancy,lactating,systemic disease, antibiotics therapy in last 3 months, consumption drugs affecting gingival health, allergy, taking steroidal and nonsteroidal anti-inflammatory drugs, periodontal treatments in last 6 months, active caries, implants, crowns, orthodontic appliance and mouth breathing habbit.

Intervention groups

In this study, control group use the dextrose mouthwash and intervention group use probiotics mouthwash.

Main outcome variables

BOP; PI; GI; OH-s

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151017024573N6**

Registration date: **2018-09-25, 1397/07/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-25, 1397/07/03**

Update count: **0**

Registration date

2018-09-25, 1397/07/03

Registrant information

Name

Mohadeseh Heidari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8351

Email address

mheidari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran university of medical science

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of the probiotics suspension containing lactobacillus salivarius on gingivitis

Public title

effects of the probiotics suspension on gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

plaque induced gingivitis presence at least 20 teeth

Exclusion criteria:

systemic disease pocket depth>3 antibiotics therapy in last 3 months consumption drugs affecting gingiva periodontal treatment in last 6 month active caries orthodontic appliance crowns/ implants mouth breathing pregnancy allergies

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by random number table

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, all patients, examiners, researchers, who perform data analysis are blind. Only a nurse who does not have any role in the research knows the type of drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moallem square

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2017-04-23, 1396/02/03

Ethics committee reference number

IR.MAZUMS.REC.1396.2950

Health conditions studied

1

Description of health condition studied

gingivitis

ICD-10 code

k05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

PI, GI, BOP

Timepoint

baseline,1,2 and 4 weeks after that

Method of measurement

probe

Secondary outcomes

1

Description

OHI

Timepoint

baseline,1,2 and 4 weeks

Method of measurement

probe

Intervention groups

1

Description

Control group: placebo mouthwash, two times a day for four weeks, immediately after brushing, rinse defined amount (not swallow) for 1 minutes

Category

Placebo

2

Description

Intervention group: lactobacillus salivarius probiotic mouthwash, two times a day for four weeks, immediately after brushing, rinse defined amount (not swallow) for 1 minutes

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran University of Medical Science,Sari Dental Faculty

Full name of responsible person

Mohadeseh Heidari

Street address

Faculty of Dentistry, University of Medical Sciences, near Tooba clinic, Khazar Square, Sari, Iran

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Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran university of Medical Science

Full name of responsible person

Farhad Sobouti

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Faculty of Dentistry, University of Medical Sciences, near Tooba clinic, Khazar Square, Sari, Iran

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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

Mazandaran university of Medical Science

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

Mazandaran University of Medical Sciences

Full name of responsible person

Maede Yusefnezhad

Position

dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Periodontist

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Person responsible for updating data

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Position

dental 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