

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effects of the probiotics suspension containing lactobacillus plantarum on gingivitis

#### Protocol summary

##### Study aim

The effect of Lactobacillus plantarum probiotic suspension on the plaque index (PI), gingival index (GI), bleeding on probing (BOP) and oral hygiene index (OHI) of 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 (patients, analyst 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 of drugs affecting gingival health, allergy, taking steroids and nonsteroidal anti-inflammatory drugs, periodontal treatments in last 6 months, active caries, implants, crowns, orthodontic appliance and mouth breathing habit.

##### 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: **IRCT20151017024573N7**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

##### Registration date

2019-04-07, 1398/01/18

##### 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

##### Expected recruitment start date

2018-09-22, 1397/06/31

##### Expected recruitment end date

2019-09-22, 1398/06/31

##### 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 plantarum 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

**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**

2017-04-22, 1396/02/02

**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**

Plaque Index

**Timepoint**

baseline,1,2 and 4 weeks after intervention

**Method of measurement**

probe

2

**Description**

Gingival Index

**Timepoint**

baseline,1,2 and 4 weeks after intervention

**Method of measurement**

probe

3

**Description**

Bleeding on Probing

**Timepoint**

baseline,1,2 and 4 weeks after intervention

**Method of measurement**

probe

**Secondary outcomes**

1

**Description**

Oral Hygiene Index

**Timepoint**

baseline,1,2 and 4 weeks after intervention

**Method of measurement**

probe

**Intervention groups**

1

**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**

Treatment - Drugs

**2**

**Description**

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

**Category**

Treatment - Drugs

**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**

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

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**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**

Sari 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mehran Ebrahimzadeh Hassanabadi

**Position**

dental student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Position**

Associate Professor

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Specialist

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Position**  
dental student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
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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