

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Comparative study of clinical and microbial effect of probiotics and phase 1 of periodontal treatment on patient with moderate to severe periodontitis in Tehran university in 1390

#### Protocol summary

##### Summary

Some patients with moderate to severe periodontitis will be selected from those who will come to Tehran university. Patients must have the following parameters: 1.PPD $\geq$  4mm; 2.CAL $\geq$ 3mm and 3.bone loss  $\geq$ 3mm. Exclusion criterion: 1.taking antibiotic over 3months ago; 2.immune deficiency disorders; 3.lactose intolerance and 4.taking immune suppressor drugs. First of all sample from saliva will be taken from 20 patient and transferred to the lab in ice-pack. In the lab probiotic of lactobacillus will be extracted from these samples and they will be tested against Aggregatibacter actinomycetemcomitans. The extracted lactobacillus will be used as probiotic mouthwash during the next stages. After that patients will be selected and recorded for these periodontal criterion: Bleeding on Probing, Plaque index, Periodontal Pocket Depth, Periodontal disease index, Gingival index and taken the samples from whole saliva and periodontal pocket(the deepest one) to determine the amount of aggregatibacter actinomycetemcomitans.pocket samples will be taken by 3paper points for 30 seconds. After this stage,phase 1 periodontal therapy(scaling and root planning) will be done for the patients .after complement of this stage some probiotic and placebo mouthwashes (from all available contents in probiotic mouthwash but bacteria )will be prescribed to the patients at random(balanced block randomization) for 4 weeks. (5cc bid) after that periodontal indexes and sampling from saliva and pockets will be recorded on 14th and 28th days and probiotic group will be compared to placebo one.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201258825N1**

Registration date: **2012-08-20, 1391/05/30**

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

Last update:

Update count: **0**

##### Registration date

2012-08-20, 1391/05/30

##### Registrant information

###### Name

Neda Sajedi nejad

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2213 7768

###### Email address

akbari@nigeb.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Terhan University of Medical Sciences

##### Expected recruitment start date

2012-08-09, 1391/05/19

##### Expected recruitment end date

2012-10-06, 1391/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study of clinical and microbial effect of probiotics and phase 1 of periodontal treatment on

patient with moderate to severe periodontitis in Tehran university in 1390

### Public title

Evaluate the effect of probiotics and phase 1 of periodontal treatment on patient with moderate to severe periodontitis

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: moderate to severe periodontitis and the presence of pockets more than 4mm. Patients must have the following parameters: 1.PPD $\geq$  4mm; 2.CAL $\geq$ 3mm and 3.bone loss  $\geq$ 3mm. Exclusion criterion: 1.taking antibiotic over 3months ago; 2.immune deficiency disorders; 3.lactose intolerance and 4.taking immune suppressor drugs.

### Age

No age limit

### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 20

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran university of medical science

##### Street address

Tehran,Keshavarz BLV.Ghods AVN.Sazmane markazie daneshgah building.floor 5

##### City

Tehran

##### Postal code

0098

#### Approval date

2012-08-08, 1391/05/18

#### Ethics committee reference number

130/993/91/5

## 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

Gingival index

#### Timepoint

Day 0,14 and 28

#### Method of measurement

Prob

### 2

#### Description

Plaque index

#### Timepoint

Day 0,14 and 28

#### Method of measurement

Plaque staining

### 3

#### Description

Periodontal pocket depth

#### Timepoint

Day 0,14 and 28

#### Method of measurement

Prob

### 4

#### Description

Colony of Aggrebacter actinomycetcomitans

#### Timepoint

Day 0,14 and 28

#### Method of measurement

Colony count

### 5

#### Description

Bleeding on probing

#### Timepoint

Day 0,14 and 28

#### Method of measurement

Prob

### 6

#### Description

Periodontal disease index

#### Timepoint

Day 0,14 and 28  
**Method of measurement**  
Prob

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Scaling and root planning and probiotic mouth wash in case group

#### Category

Treatment - Drugs

### 2

#### Description

Scaling and root planning and placebo mouthwash in control group

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental school of Tehran university of medical science

##### Full name of responsible person

Dr.Neda Sajedi nejad

##### Street address

North amirabad.dental school of Tehran university

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Dental research center, Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Mojgan Paknejad

##### Street address

Dental Research Center, Dental Faculty,Tehran University of Medical Sciences.Ghods str.Engheleb Ave.Tehran.

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Dental research center, Tehran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tehran university of medical science

##### Full name of responsible person

Dr Neda sajedi nejad

##### Position

PHD

##### Other areas of specialty/work

##### Street address

Dentistry university of Tehran

##### City

Tehran

##### Postal code

0098

##### Phone

+98 21 2213 7768

##### Fax

##### Email

neda\_sajedi@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

National institute of genetic and bioengineering

##### Full name of responsible person

Dr Kambiz akbari

##### Position

PHD

##### Other areas of specialty/work

##### Street address

Hemmat gharb highway.Pajouhesh bulvar.National institute of genetic and bioengineering

##### City

Tehran

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+98 21 2213 7768

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##### Email

hakimehsharafi@yahoo.com

##### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran university of medical science

**Full name of responsible person**

Dr Neda sajadi nejad

**Position**

Resident of periodontology

**Other areas of specialty/work****Street address**

North amirabad.dental school of tehran university

**City**

Tehran

**Postal code****Phone**

+98 21 2213 7768

**Fax****Email**

neda\_sajedi@yahoo.com hakimehsharafi@yahoo.com  
**Web page address**

## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*