# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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>= 4mm; 2.CAL>=3mm and 3.bone loss >=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 patien 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 Aggrecatibacter actinomycetcomitans. The exteracted 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 aggrecatibacter actinomycetcomitans.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 availaible contentsl in probiotic mouthwashe but bacteria )will be prescribed to the patients at random(balanced block randomization) for 4 weeks. (5cc bid) after that periodontal indexies 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 Sciencs


**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>= 4mm; 2.CAL>=3mm and 3.bone loss >=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/د

## 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

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0098

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neda_sajedi@yahoo.com

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

National institue of genetic and bioengeneering

**Full name of responsible person**

Dr Kambiz akbari

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PHD

**Other areas of specialty/work**

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Hemmat gharb highway.Pajouhesh bulvar.National institue of genetic and bioengeneering

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## Person responsible for updating data

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Resident of periodontology

**Other areas of specialty/work**

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## 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*