

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

clinical, microbiological and IL-6 evaluation of probiotic lozenges in patients with chronic periodontitis

Protocol summary

Study aim

Treatment

Design

Clinical Trails, Randomized control, double Blind, sample size 24 person, single center

Settings and conduct

this clinical study will be conducted in Islamic Azad university of Tehran and Shahid beheshty university of Tehran. the trail will be randomized and blinded and only the investigator alert about grouping and distribution of probiotics and placebos

Participants/Inclusion and exclusion criteria

patients have to have atleast 12 teeth , atleast one of tooth in each quadrant has (5-7mm) pocket , gingival index >2 & attachmant loss >1mm radiographic evidence of bone loss.

Intervention groups

The effect of Probiotic Lozenges and compare the effect with placebo

Main outcome variables

plaque index_ gingival index- attachment loss. pocket depth. Prevotella intermedia. Actinomycetemcomitans A. P.gingivalis. IL-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210905052375N1**

Registration date: **2021-09-14, 1400/06/23**

Registration timing: **prospective**

Last update: **2021-09-14, 1400/06/23**

Update count: **0**

Registration date

2021-09-14, 1400/06/23

Registrant information

Name

HEDIEH GHANDI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2228 4367

Email address

drhediehghandi36@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-20, 1400/07/28

Expected recruitment end date

2022-02-17, 1400/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

clinical, microbiological and IL-6 evaluation of probiotic lozenges in patients with chronic periodontitis

Public title

probiotics in the treatment of patient with chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patient have to have atleast 12 teeth atleast one of the tooth in each quadrant has (5-7mm) pocket gingival index >2 in each quadrant clinical attachmet loss >1mm radiographic evidence of bone loss

Exclusion criteria:

patients with systemic disease patients who were pregnant , lacking , smokers patients who had undergo periodontal or antibiotic treatment

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

simple

Blinding (investigator's opinion)

Double blinded

Blinding description

the participant will be divided into case and control groups. the outcome assessor will coded and distributed placebos between the participants. the coded finding the will be statistically analysed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee_faculty of dentistry , Tehran
Medical Sciences , Islamic Azad University, Tehran

Street address

Neyesstan st , pasdaran

City

TEHRAN

Province

Tehran

Postal code

19585175

Approval date

2020-05-16, 1399/02/27

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.011

Health conditions studied

1

Description of health condition studied

chronic periodontitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Prevotella intermedia. Actinomyces comitans A.
P.gingivalis.IL-6.gingival index. plaque index. clinical
attachment loss

Timepoint

base line ,1 & 3 months

Method of measurement

plaque index by Sliness and LEO. gingival index by Leo
and Sliness . attachment loss and pocket depth by
william prob, Prevotella intermedia, Porphyromonas
gingivalis. Actinomyces comitans A. by PCR & Real
time PCR. IL-6 BY ELISA TEST

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Control group: Placebo group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic azad university of tehran

Full name of responsible person

Hedieh Ghandi

Street address

Neyestan 9- pasdaran

City

tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2256 4571

Email

drhediehghandi36@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Islamic azad university of tehran

Street address

neystan 9 st. pasdaran st

City

tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

Mahiran99@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr mahmood Ghasemi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

neystan 9- pastadan st

City

tehran

Province

Tehran

Postal code

1946853314

Phone

002122454571

Email

mahiran99@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

hedieh ghandi

Position

resident

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

Street address

neystan 9. pasdaran

City

tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

drhediehghandi36@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

DR.Mahmoud Ghasemi

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Neystaan 9. Pastadarn

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2256 4571

Email

mahiran99@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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