

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Clinical Effects of Mechanical Debridement with Adjunctive Photodynamic Therapy or Chlorhexidine Irrigation in patients with Peri-implantitis: a Randomized Clinical Trial

Protocol summary

Study aim

evaluating the Clinical effects of mechanical debridement with adjunctive photodynamic therapy or chlorhexidine irrigation in peri implantitis

Design

single blind,parallel, randomized clinical trial with 26 participants divided in control and treatment groups with sealed envelope randomization method.

Settings and conduct

patients will be selected from those referring to implant department, faculty of dentistry, islamic azad university of tehran this clinical trial will be single blinded(patients)

Participants/Inclusion and exclusion criteria

inclusion criteria: 18-80 years of age, presence of at least one site with peri implantitis and screw type implants with rough surface which had been in function for at least 1 year exclusion criteria: usage of antibiotics or NSAIDs in last 3 months, implant mobility, pregnancy or nursing, history of peri implantitis or periodontal treatment in last 6 months, uncontrolled diabetes, tobacco use and history of autoimmune diseases, malignancy, cardiovascular insufficiency or acute diseases of other organs

Intervention groups

Periodontal treatment comprising scaling and root planing (SRP) and cleaning of the implant surfaces with prophylaxis brush and paste will be accomplished for each patient. 2 weeks after SRP, clinical indices will be recorded and patients will be randomly divided into two groups and treated with photodynamic therapy(810nm diode laser,0.3 W, 90s with indocyanine green) or chlorhexidine irrigation(control) with blunt needle. 2 weeks later these treatments will be repeated for control and treatment groups. chlorhexidine mouthwash(0.2%, 2 times per day and each time 10ml) will be prescribed for both groups for 4 weeks. clinical indices will be evaluated at 1,3 and 6 month after treatment.

Main outcome variables

probing pocket depth(PPD), clinical attachment loss(CAL), papillary bleeding index(PBI) and Plaque index (modified mombelli)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201021049104N1**

Registration date: **2020-11-06, 1399/08/16**

Registration timing: **prospective**

Last update: **2020-11-06, 1399/08/16**

Update count: **0**

Registration date

2020-11-06, 1399/08/16

Registrant information

Name

Ali Zareey

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7740 8848

Email address

ali76_zareey@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical Effects of Mechanical Debridement with Adjunctive Photodynamic Therapy or Chlorhexidine Irrigation in patients with Peri-implantitis: a Randomized Clinical Trial

Public title
Clinical Effects of Photodynamic Therapy in Peri-implantitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 18-80 years of age Presence of at least one site with peri-implantitis (PPD $\geq$ 6mm, MBL $\geq$ 3 mm and bleeding/suppuration on probing) At least 1 year of function in implants Screw type implants with rough surface
Exclusion criteria:
 Use of antibacterial or non-steroidal anti-inflammatory drugs within 3 months prior to diagnosis Implant mobility Pregnancy or breastfeeding History of autoimmune diseases, malignancy, cardiovascular insufficiency or acute diseases of other organs History of peri-implantitis or periodontal treatment in last 6 months Uncontrolled diabetes (HbA1c > 7%) Tobacco use

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method will be used; at first, patients will be stratified based on age(above 50 and under 50) and then a block size of 4 or 6 will be selected randomly and patients will be divided into treatment and control groups based on that.

Blinding (investigator's opinion)
Single blinded

Blinding description
the participants in this clinical trial do not know if they are receiving the adjunctive photodynamic therapy or chlorhexidine irrigation

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Tehran

Street address

No. 9, 9th Neyestan St. , Pasdaran Ave. , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2020-10-12, 1399/07/21

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.192

Health conditions studied

1

Description of health condition studied

peri implantitis

ICD-10 code

M27.62

ICD-10 code description

Post-osseointegration biological failure of dental implant

Primary outcomes

1

Description

Probing pocket depth(PPD)

Timepoint

at baseline, 2 weeks,1,3 and 6 month after treatment

Method of measurement

plastic probe

2

Description

Clinical attachment loss(CAL)

Timepoint

at baseline, 2 weeks,1,3 and 6 month after treatment

Method of measurement

plastic probe

3

Description

Papillary bleeding index(PBI)

Timepoint

at baseline, 2 weeks,1,3 and 6 month after treatment

Method of measurement

Observation of papillary bleeding pattern

4

Description

Modified mombelli plaque index(mPI)

Timepoint

at baseline, 2 weeks,1,3 and 6 month after treatment

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Scaling and root planing and mechanical debridement of dental implants with Ti curettes+ Photodynamic therapy (810 nm diode laser,0.3W, 90s continuous and with indocyanine green photosensitizer; photodynamic therapy will be repeated 2 weeks later)+ chlorhexidine mouthwash

Category

Treatment - Other

2

Description

Control group: Scaling and root planing and mechanical debridement of dental implants with Ti curettes+ chlorhexidine(0.2%) irrigation with a blunt needle+ chlorhexidine mouthwash

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Tehran Dental Branch

Full name of responsible person

nasrin esfahanizadeh

Street address

No. 9, 9th Neyestan St. , Pasdaran Ave. , Tehran

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Phone

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Email

n_esfahanizadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

arash azizi

Street address

No. 9, 9th Neyestan St. , Pasdaran Ave. , Tehran

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Email

ali76_zareey@yahoo.com

Web page address

http://dental.iautmu.ac.ir

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

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

Islamic Azad University

Full name of responsible person

nasrin esfahanizadeh

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

Street address

No. 9, 9th Neyestan St. , Pasdaran Ave. , Tehran

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

nasrin esfahanizadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

ali zareey

Position

dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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No. 9, 9th Neyestan St. , Pasdaran Ave. , Tehran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Collected data after de identification is available to share

When the data will become available and for how long

6 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Statistical analysis of data is allowed after applicator presents required credentials for working in academic institutions

From where data/document is obtainable

Via contacting : n_esfahanizadeh@yahoo.com

What processes are involved for a request to access data/document

Sending credentials to mentioned e-mail

Comments