Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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≥ 6mm, MBL≥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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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