

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of Scaling with Photodynamic Therapy or Subgingival Irrigation with Chlorhexidine on IL-6 and IL-1B levels in patients with Peri-implantitis

Protocol summary

Study aim

To determine the effect of Scaling with Photodynamic Therapy using Diode Laser on the levels of Inflammatory Cytokines Interleukin-1 and Interleukin-6 in patients with Peri-implantitis, followed by its comparison to Scaling with Sublingual Irrigation using Chlorhexidine

Design

Single-blinded, parallel, randomized clinical trial with 66 participants divided into control and treatment groups using the sealed envelope randomization method.

Settings and conduct

Patients will be selected from those referring to the Implant Department, Faculty of Dentistry, Islamic Azad University of Tehran. This clinical trial will be single-blinded (the dentist who assesses the outcomes).

Participants/Inclusion and exclusion criteria

Partial Edentulous patients who are between 18 and 80 years old with healthy or treated periodontal conditions, in a maintenance care program, and have a 25 or less total plaque score. Presence of at least one implant with peri-implantitis that has been in function for at least one year; use of antibiotics or non-steroidal anti-inflammatory drugs, the presence of diseases that affect periodontal conditions, pregnant or lactating women, mobile implants, smoking.

Intervention groups

Intervention group: Scaling, Root Planing, and Mechanical Debridement of dental implants with Ti curettes + Photodynamic Therapy (320nm diode laser, 50mW, 90s continuously along with Methylene Blue 1% Photosensitizer; Photodynamic Therapy will be repeated 2 weeks later) + Chlorhexidine mouthwash Control group: Scaling, Root Planing, and Mechanical Debridement of dental implants with Ti curettes + Chlorhexidine (0.2%) irrigation with a blunt needle + Chlorhexidine mouthwash

Main outcome variables

Interleukin 1-b; Interleukin 6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210212050339N1**

Registration date: **2021-08-18, 1400/05/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-18, 1400/05/27**

Update count: **0**

Registration date

2021-08-18, 1400/05/27

Registrant information

Name

Pardis Hojjat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8808 3183

Email address

pardis.hojjat@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-06, 1400/04/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Scaling with Photodynamic Therapy or Subgingival Irrigation with Chlorhexidine on IL-6 and IL-1B levels in patients with Peri-implantitis

Public title

The Effect of Scaling with Photodynamic Therapy on IL-6 and IL-1B levels in patients with Peri-implantitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

At least one implant with peri-implantitis The implant has been in function for at least one year Screw-type implants with rough surface Partial edentulous patients with healthy or treated periodontal condition who are in maintenance care program. Total plaque score \leq 25 18-80 years of age

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 Use of Systemic Antibiotic Therapy for Prophylaxis of Endocarditis Infectious diseases such as HIV, TB and Hepatitis Failure to sign a written consent Those treated with any drugs which may affect soft tissue conditions; such as Phenytoin, Cyclosporine, etc. for 2 weeks or more in a month, before the initial evaluation. Head and neck radiotherapy Alcohol or drug abuse

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization method will be used; at first, patients will be stratified according to their ages (above 50 and under 50), followed by random selection of a block size of 4 or 6, and afterwards, patients will be divided into treatment and control groups accordingly.

Blinding (investigator's opinion)

Single blinded

Blinding description

The dentist performing the assessment will be blind to the patient group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Azad Tehran University of Medical Sciences

Street address

Unit B5-1, Sa'adi Tower, Hormozan Street, Shahrak-e-Gharb

City

Tehran

Province

Tehran

Postal code

1466764141

Approval date

2021-06-01, 1400/03/11

Ethics committee reference number

IR.IAU.DENTAL.REC.1400.028

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**

Interleukin 1-b Levels in Gingival Crevicular Fluid

Timepoint

At baseline, 3 months, and 6 months after treatment

Method of measurement

The Enzyme-linked Immunosorbent Assay test

2**Description**

Interleukin 1-b Levels in Gingival Crevicular Fluid

Timepoint

At baseline, 3 months, and 6 months after treatment

Method of measurement

The Enzyme-linked Immunosorbent Assay test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Scaling, Root Planing, and Mechanical Debridement of dental implants with Ti curettes + Photodynamic Therapy (320nm diode laser, 50mW, 90s continuously along with Methylene Blue 1% Photosensitizer; Photodynamic Therapy will be repeated 2 weeks later) + Chlorhexidine mouthwash

Category

Treatment - Other

2

Description

Control group: Scaling, 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

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2256 4571

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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19585175

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Email

pardis.hojjat@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

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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

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Pardis Hojjat

Position

Dentistry resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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