

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effects of photo dynamic therapy and nonsurgical mechanical debriment on pocket depth and bleeding of probing in peri-implant disease

Protocol summary

Study aim

compare the clinical effects including bleeding on probing and pocket depth between nonsurgical mechanical debridement and photodynamic therapy in peri-implant disease.

Design

During a randomized controlled clinical trial, fifty patients entered the study, using the Randlist 1.2 software, were divided into two groups of 25, based on the randomization principles and feasibility studies, and based on the list of the hereditism of the above software. , Will be treated with mechanical debridement and photodynamic therapy.

Settings and conduct

Patients eligible for study in periodontics department of Tabriz Dental School entered the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: Bleeding on probing Depth of probing greater than or equal to 4 mm sub functional implant for <1 year Exclusion criteria: smoking Pregnancy and lactation Addicted to drugs and alcohol Uncontrolled diabetes and debilitating systemic diseases

Intervention groups

The initial treatment protocol in both groups includes health education and removal of the mass and plaque using the ultrasonic curing apparatus (250.EMSElectroMedical SA.Nyon.Switzerland and with metal cams) followed by using Aire -Powder Polishin Polishing of the teeth and implant was performed on the top of the gum and under the gum فاند semi patients treated with photodynamic therapy using Photosensitizer with a low-power diode laser (nm805, w5 / 0) using an inhaled cyanine green immediately after mechanical debridement.Photodynamic Therapy (PDT) is a new therapeutic method for the removal of infectious pathogens using photosensitizer and radiation with a specific length. PDT can be used locally in periodontal

pocket .

Main outcome variables

Bleeding on probe: Depth of pocket: Pain during probe: Pus

General information

Reason for update

Acronym

PI

IRCT registration information

IRCT registration number: **IRCT20180913041033N1**

Registration date: **2019-01-07, 1397/10/17**

Registration timing: **retrospective**

Last update: **2019-01-07, 1397/10/17**

Update count: **0**

Registration date

2019-01-07, 1397/10/17

Registrant information

Name

davod fathollahzade

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

davood.fathollahzade@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-25, 1396/02/05

Expected recruitment end date

2017-11-10, 1396/08/19

Actual recruitment start date

2017-04-29, 1396/02/09

Actual recruitment end date

2018-03-10, 1396/12/19

Trial completion date

2018-03-10, 1396/12/19

Scientific title

The effects of photo dynamic therapy and nonsurgical mechanical debriment on pocket depth and bleeding of probing in peri-implant disease

Public title

peri implant disease

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria bleeding of probing(bop) Depth of probing greater than or equal to four millimeters Under the implant's function for 1 year or more Failure of recession soft tissue with or without a minimum bone recession less than or equal to 2 mm

Exclusion criteria:

Exclusion criteria Pregnancy and lactation Addicted to drugs and alcohol Uncontrolled diabetes and disabling systemic disease smokers

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **50**Actual sample size reached: **49****Randomization (investigator's opinion)**

Randomized

Randomization description

50 patients selected, half of them were randomly selected using the software and received photodynamic therapy.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences.

Street address

Tabriz- Valiasr Coy; Mossadeq Square; Eastern Clove Coyote; No. 60, Floor 6

City

Tabriz

Province

East Azarbaijan

Postal code

5157967694

Approval date

2017-04-23, 1396/02/03

Ethics committee reference number

IR.TBZM.1396.79.ED.REC.

Health conditions studied**1****Description of health condition studied**

Peri-implantitis

ICD-10 code

k05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes**1****Description**

bleeding on probing

Timepoint

Two weeks after mechanical and photodynamic therapy and at the end of the follow-up phase

Method of measurement

Bleeding on probing:The probe is carefully inserted into the pocket and slowly moves to the side of the implant and records bleeding if observed.

Secondary outcomes**1****Description**

suppuration

Timepoint

Baseline two weeks later, three months later

Method of measurement

The presence of (1) or loss of (0) by itself, after a probe or gingival pressure around the implant, Recorded with finger

2**Description**

Pain on Probing(POP)

Timepoint

Baseline two weeks later, three months later

Method of measurement

How to measure pain using the Visual Analogue Scale (VAS) method: A ruler that is about ten centimeters in length is provided to the patient, and it is explained that if the pain is greatest in the entire length of the ruler and the lowest in the left end In this case, mark the amount of pain on the ruler. The distance from the marked point to the left is measured and reported in cm.

3

Description

Probing Depth (PD)

Timepoint

Baseline two weeks later, three months later

Method of measurement

Depth of probe: In six points around the implants (Mesobuccal, Mid Buccal, Disto Buccal, Meso Lingual, Disto Lingual and Mid Lingual), the margin of the mucosa of the implant was measured to the depth of the gingival area with the probe and the deepest probe region was recorded as the probing depth

Intervention groups

1

Description

control group:: The initial treatment protocol in both groups includes health education and removal of the mass and plaque using the ultrasonic curing apparatus (250.EMSElectroMedical SA.Nyon.Switzerland with metal cams) followed by using Aire -Powder Polishin Polishing of the teeth and implant was performed on the top of the gum and under the gum.

Category

Treatment - Other

2

Description

Intervention group: The initial treatment protocol in both groups includes health education and removal of the mass and plaque using the ultrasonic curing apparatus (250.EMSElectroMedical SA.Nyon.Switzerland with metal cams) followed by using Aire -Powder Polishin Polishing of the teeth and implant was performed on the top of the gum and under the gum. semi patients treated with photodynamic therapy using Photosensitizer with a low-power diode laser (nm805, w5 / 0) using an inhaled cyanine green immediately after mechanical debridement. Photodynamic Therapy (PDT) is a new therapeutic method for the removal of infectious pathogens using photosensitizer and radiation with a specific length. PDT can be used locally in periodontal envelopes and prevent overhead associated with administration of systemic anti-microbial drugs. Slowly It also reduces the appearance of bacterial resistance.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontology, Faculty of Dentistry, Tabriz

Full name of responsible person

Davood.fathollahzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

90

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**

Tabriz University of Medical Sciences

Full name of responsible person

Davood fathollahzadeh

Position

pathologist

Latest degree

Specialist

Other areas of specialty/work

Pathology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Davood fathollahzadeh

Position

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Latest degree

Specialist

Other areas of specialty/work

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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Oral pathologist

Latest degree

Specialist

Other areas of specialty/work

Pathology

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Fax**Email**

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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

we consider to check genetic of disease in order to precisely find the cause of disease

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

demographic file

When the data will become available and for how long

one month after publishing the paper

To whom data/document is available

dentists

Under which criteria data/document could be used

researchers and any analysis is free

From where data/document is obtainable

davood fatallahzade

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

first provide a reliable presentation then contact to responsible author

Comments

nothing