Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of photodynamic therapy with indocyanine green photosensitizer on nonsurgical management of peri-implant diseases and the periodontopathic bacteria

Protocol summary

Summary

The aim of this single blind randomized clinical study is to assess the effect of photodynamic therapy using Indocyanin green as a photosensitizer on non-surgical treatment of peri-implant mucosal inflammation from the clinical point of view and it's periopathogenic bacteria in vivo. this single blind randomized study is done on the samples selected from the patients referring to the Periodontology department of dental faculty of Tabriz University of Medical Sciences between November 2016 and March 2017. The inclusion criteria are described as following: 1) Implants with severe peri-implant mucositis or mild peri-implantitis 2) Presence of at least ONE implant with at least ONE year in function. The patients with the following conditions are excluded from the study: 1) Any intervention for treatment of peri-implant disease in the last three months 2) Smokers. 25 patients in each group (50 patients) will attend the study. Patients will randomly assign in to two groups with the flip of coin. Control group will receive mechanical debridement (using ultrasonic devices under local anesthesia) and the test group will receive photodynamic therapy with Indocyanine green photosensitizer(intervention) just after the mechanical debridement. Primary and secondary outcomes will be assessed after two weeks, one and 3 months. Primary outcome in this study is bleeding on Probing. Secondary outcomes are pocket depth, pain on probing, clinical attachment level and common microorganisms around implants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610211248N4**
Registration date: **2017-02-10, 1395/11/22**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Reza Pourabbas

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-10-15, 1395/07/24

Expected recruitment end date

2017-10-16, 1396/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of photodynamic therapy with indocyanine green photosensitizer on nonsurgical management of peri-implant diseases and the periodontopathic bacteria

Public title

The effects of laser assisted disinfection treatments on

peri-implant disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: At least 18 years old; Presence of at least ONE implant with at least ONE year in function ;Presence of Peri- implant disease (severe peri-implant mucositis or mild peri- implantitis which is placed in ISI class II, III and IVaccording to theKadkhodazade and Amid classification with a positive bleeding on probing, probing depth of 4 mm or more,no soft tissue loss with or without bone loss of 2mm or less in periapical radiographs) Exclusion Criteria:Using antibiotic from 3 months prior to study ; Using NSAIDS and/or corticosteroids at the recent 3 months, ;Presence of any history of any treatment for peri- implant disease during last 3 months ;Being a current and/or former smokers , drug or alcohol abuser ; Using Bisphosphonates, Cyclosporine, Coumadin, Warfarin and Heparin ;Pregnancy and lactation; Presence of an active periodontal disease after therapy ;Presence of poorly controlled diabetes and other debilitating diseases ;Refraining to sign the consent form

Age

From **18 years** old to **120 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Daneshgah Ave.

City

Tabriz

Postal code

Approval date

2016-09-26, 1395/07/05

Ethics committee reference number

IR.TBZMED.REC.1395.681

Health conditions studied

1

Description of health condition studied

Peri-implant disease

ICD-10 code

Z96.5, K05

ICD-10 code description

Presence of tooth-root and mandibular implants, Gingivitis and periodontal diseases

Primary outcomes

1

Description

Bleeding on Probing

Timepoint

2 weeks, 1 mounths,3 months

Method of measurement

Clinical Examination

Secondary outcomes

1

Description

probing depth

Timepoint

2weeks,1month and 3 months

Method of measurement

clinical and laboratory assessment

2

Description

clinical attachment level

Timepoint

2weeks,1month and 3 months

Method of measurement

clinical examination

3

Description

Pain on Probing

Timepoint

2weeks,1month and 3 months

Method of measurement

clinical examination

4

Description

common microorganisms

Timepoint

2weeks,1month and 3 months

Method of measurement
laboratory assessment

Intervention groups

1

Description
The affected sites will be debrided mechanically using ultrasonic devices under local anesthesia. Consequently, a photosensitizer agent (Indocyanine green) will be inserted into peri-implant pockets by a gauge 21 round-tip needle for 30 seconds followed by illumination with laser beam (980 nm/ 0.5 watts) for 30 seconds.The patient will be instructed to avoid intake of any food/beverages for 2 hours.
Category
Treatment - Other

2

Description
The affected sites will be debrided mechanically using ultrasonic devices under local anesthesia. The patient will be instructed to avoid intake of any food/beverages for 2 hours.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Reza Pourabbas
Street address
Daneshgah Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Daneshgah Ave.
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Tabriz
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
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty