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 its cytokine profile

Protocol summary

Summary

The dental implants are considered as successful treatments with high predictability and survival rate for patients. By current increasing use of dental implants, arising more complications are inevitable. One of the growing problem with controversial treatment is, peri-implant diseases (PID). Different types of treatment including surgical and non-surgical methods for management of PID have been described. It seems, in patients with PID that have indication for non-surgical treatment, the mechanical debridement alone is not sufficient and in the most of time adjunctive therapy is recommended. Photodynamic therapy (PDT) is a novel therapeutic method for removal of infectious pathogens with the use of photosensitizer and specific wavelength of light. This study will be launched from mid-October 2016. In this study 25 patients will be assessed in test and control groups. The control group will receive mechanical debridement (MD) alone and the test group will receive MD with PDT. Probing depth, Clinical attachment level, Bleeding on probing, Pain on probing, Plaque index, IL-1β, IL-6, TNF-α and MMP8 will be assessed at baseline, 2 weeks and 3 month post-operatively. A Linear Mixed Model analytic test, Chi-square and Mantle Haenszel test will be used. P≤ 0.05 will be considered to represent a statistically significant differences among tested parameters. The present study will evaluate the post treatment clinical parameters and peri-implant mucosal crevicular fluid cytokine profiles in patients with PIMI, treated by either mechanical debridement alone or mechanical debridement in addition to PDT.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609281248N3**
Registration date: **2016-10-15, 1395/07/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-15, 1395/07/24

Registrant information

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Reza Pourabbas

Name of organization / entity

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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

2017-10-15, 1396/07/23

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 its cytokine profile

Public title
Application of laser assisted anti-infection therapy for the gum disease around dental implants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: • Age≥18 yr. • Persistence of at least ONE implant with at least ONE year • Persistence of Peri-implant disease Exclusion Criteria: • Using antibiotic from 3 months prior to study • Using NSAIDS and/or corticosteroids on resent 3 mounts, • Presence of any history of any treatment for Peri- implant disease during last 3 mounts • 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 of consent signature
Age
No age limit
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)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
none
Secondary trial Id
none
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Daneshgah Street
City
Tabriz
Postal code
Approval date
2016-09-20, 1395/06/30
Ethics committee reference number
IR.TBZMED.REC.1395.554

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, 2 mounths
Method of measurement
Clinical Examination

Secondary outcomes

1

Description
Interleukin 1
Timepoint
baseline, 2 weeks, 2 months
Method of measurement
Labratoary exam

2

Description
Probing Depth
Timepoint
baseline, 2 weeks, 2 months
Method of measurement
clinical examination

3

Description
clinical attachment level
Timepoint
baseline, 2 weeks, 2 months
Method of measurement

clinical examination

4

Description
pain on probing
Timepoint
baseline, 2 weeks, 2 months
Method of measurement
clinical examination

5

Description
Interleukin 6
Timepoint
baseline, 2 weeks, 2 months
Method of measurement
Labratoary exam

6

Description
TNF alpha
Timepoint
baseline, 2 weeks, 2 months
Method of measurement
Labratoary exam

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 " followed by illumination with laser beam (980 nm/ 0.5 watts) for 30 ". The patient will be instructed to wash out his/her mouth and avoid to intake 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 wash out his/her mouth and avoid to intake any food/beverages for 2 hours.
Category
Treatment - Drugs

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
Faculty of Dentistry
City
Tabriz

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
Tabriz University of Medical Science
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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

Contact
Name of organization / entity
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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