

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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-1 $\beta$ , IL-6, TNF- $\alpha$  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.  $P \leq 0.05$  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

###### Name

Reza Pourabbas

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1330 9338

###### Email address

pourabbas@tbzmed.ac.ir

##### 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  $\geq$  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 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 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 months

#### Method of measurement

Clinical Examination

## Secondary outcomes

### 1

#### Description

Interleukin 1

#### Timepoint

baseline, 2 weeks, 2 months

#### Method of measurement

Labratory 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**

Labratory exam

#### 6

##### **Description**

TNF alpha

##### **Timepoint**

baseline, 2 weeks, 2 months

##### **Method of measurement**

Labratory 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

###### **City**

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**

Tabriz University of Medical Sciences

###### **Full name of responsible person**

Dr. Reza Pourabbas

###### **Position**

Professor

###### **Other areas of specialty/work**

###### **Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*