

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Adjunctive Photodynamic Therapy using Light emitting diode in the Treatment of Advanced Chronic Periodontitis

#### Protocol summary

##### Summary

Periodontitis is defined as the inflammation of the gingiva and the adjacent attachment apparatus. Major goal of periodontal therapy is removal of bacterial biofilms from subgingival surface. The complete removal of bacterial biofilms is difficult to be accomplished. Recently, some studies have mentioned the potential antimicrobial effect of photodynamic therapy (PDT) in the treatment of periodontitis. However, there are only limited and contrary data on this subject. The aim of this study was to evaluate the short term effects of adjunctive PDT on periodontal parameters such as bleeding on probing (BOP), probing depth (PD) and clinical attachment loss (CAL) in advanced chronic periodontitis. This study is a randomized, controlled and double-blind clinical trial. 16 patients with clinical diagnosis of advanced chronic periodontitis with at least 2 periodontal pockets (4-6mm) in each quadrant are included. In each person, all teeth will be received periodontal treatment including scaling and root planning. Then, in a randomized split mouth design which each person will blind to his/her treatment, in each person, one quadrant will be treated by PDT using Light-emitting diode (LED) (625-635nm, 200mw/cm<sup>2</sup>, 30 s for each site, Fotoson CMS Dental, Denmark) in the presence of toluidine blue O (TBO) and, one quadrant will be treated only by using Light-emitting diode (LED) (625-635nm, 200mw/cm<sup>2</sup>, 30 s for each site, Fotoson CMS Dental, Denmark) without presence of toluidine blue O, one quadrant will be treated only by toluidine blue O and one quadrant (control site), will not receive any adjunctive treatment. Clinical assessment of BOP, PD and CAL will be made at baseline and a month and three months after treatment by a blind investigator.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201011261150N4**

Registration date: **2011-04-13, 1390/01/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-13, 1390/01/24

##### Registrant information

###### Name

Neda Moslemi

###### Name of organization / entity

Tehran university of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8897 3902

###### Email address

nmoslemi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Laser Research Center of Dentistry (LRCD), School of Dentistry, Tehran University of Medical Sciences

##### Expected recruitment start date

2010-04-21, 1389/02/01

##### Expected recruitment end date

2010-09-23, 1389/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Adjunctive Photodynamic Therapy using Light emitting diode in the Treatment of Advanced Chronic Periodontitis

## Public title

Application of Photodynamic therapy in the treatment of gum disease

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: clinically diagnosis of advanced chronic periodontitis with more than 3 mm clinical attachment loss; presence of at least two teeth with probing depth of 4 to 6 mm without furcation involvement in each quadrant; at least 16 remaining teeth. Exclusion criteria: periodontal treatment in the past 12 months; evidence of systemic disease related to periodontal problems; use of antibiotics for the past 6 months; pregnancy; addiction to any kind of drugs; smoking more than 10 cigarettes per day.

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **16**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Vice chancellor for research,  
Tehran University of Medical Sciences

##### Street address

Ghods st, Keshavarz blvrd

##### City

Tehran

##### Postal code

1417653761

#### Approval date

2010-11-14, 1389/08/23

#### Ethics committee reference number

1035/130

## Health conditions studied

### 1

#### Description of health condition studied

chronic periodontitis

#### ICD-10 code

K05.3

#### ICD-10 code description

Chronic periodontitis

## Primary outcomes

### 1

#### Description

Probing pocket depth

#### Timepoint

Baseline, one month, three month

#### Method of measurement

Probing pocket depth was measured to nearest millimeter from gingival margin to base of the clinical pocket by William`s periodontal probe.

### 2

#### Description

Clinical attachment loss

#### Timepoint

Baseline, one month, three month

#### Method of measurement

it was calculated as distance in millimeter from a cement-enamel junction to the bottom of probable pocket at experimental sites

### 3

#### Description

Bleeding upon probing

#### Timepoint

Baseline, one month, three month

#### Method of measurement

recording the presence or the absence of bleeding up to 30 second after probing with a William`s periodontal probe. Bop was measure in 6 sites per each tooth

## Secondary outcomes

### 1

#### Description

plaque index

#### Timepoint

baseline, One month, Three month

#### Method of measurement

plaque index for teeth number 16,12,24,36,32,44 was evaluated according to silness index were scored between 0 to 3

## Intervention groups

## 1

### Description

In group 1: first, the photosensitizer will be applied at the bottom of each periodontal pocket. Then, LED light was used to activate photosensitizer

### Category

Treatment - Other

## 2

### Description

the photosensitizer was applied at the bottom of each periodontal pocket without using LED

### Category

Other

## 3

### Description

LED irradiation was applied for 30 seconds without using PS

### Category

Other

## 4

### Description

quadrant (control site), will not receive any adjunctive treatment

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Periodontology, Dentistry faculty, Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Neda Moslemi

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Laser Research Center of Dentistry (LRCD)

##### Full name of responsible person

Dr. Sima Shahabi

##### Street address

School of Dentistry, Tehran University of Medical Sciences

##### City

Tehran

##### Grant name

##### Grant code / Reference number

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

Yes

#### Title of funding source

Laser Research Center of Dentistry (LRCD)

#### 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

School of Dentistry, Tehran University of Medical Sciences

#### Full name of responsible person

Seyed Hossein Bassir

#### Position

Dental student

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

School of Dentistry, Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Neda Moslemi

#### Position

Assistant Professor

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**Web page address****Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Seyed Hossein Bassir

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email**

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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*