

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 2026

### Treatment of periodontitis and chronic periodontitis and the complications

#### Protocol summary

##### Summary

This study is a Double-Blind randomized clinical trial that is to be done by Full mouth design method. Totally 50 patient are to be checked with the below criteria: having periodontal pocket with 5 mm depth and more; having an ideal hygienic mouth stand; not having dental plaque and having 20% full mouth plaque score (FMPS). It also needs to be mentioned these patient have chronic periodontitis that have not answered to phase one treatment and periodontal pocket is left. It needs to be said that the patient`s age range is 35 and more the below criteria are seen for the patients who are to be checked in this study. Remaining periodontal pocket after performing phase one; not having systematic disease; not being in pregnancy period; not smoking and using any drugs; being under a six month antibiotic`s treatment. The patient will be under SRP (Scaling and Root planning) treatment after a clinical check-up and registering the below parameters: 1. Bleeding on probing (BOP). 2. Clinical attachment loss (CAL). 3. Plaque index (PI). 4. Full mouth plaque score (FMPS). 5. Full mouth bleeding score (FMBS). 6. Periodontal probing depth (PPD). In order to see that there is no dental plaque. The patients are to be checked-up in the 1st 3rd and 7th days one week after SRP every single gets radiated in 3 sessions over 3 days that every radiation is in the 1st 3rd 7th days over a week in this research. We randomly split the patients into 2 groups called beholder and goal. The goal group: the patients continuously go under photodynamic therapy with 810 nanometer Diode laser Having 300 mw power in 10 seconds and 3 joule energy in 6 adjacent dental points followed by EmuDo photosensitizer . The beholder group: the patients go under SRP treatment with physiology serum and off laser. The approved patients are to be reviewed and compared in one three and six month intervals.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013110215236N1**

Registration date: **2014-02-05, 1392/11/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-02-05, 1392/11/16

##### Registrant information

##### Name

Abbas Monzavi

##### Name of organization / entity

Laser Research Center of Dentistry, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8801 5017

##### Email address

monzavia@sina.tums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Tehran University of Medical Sciences /  
monzavia@sina.tums.ac.ir

##### Expected recruitment start date

2011-09-23, 1390/07/01

##### Expected recruitment end date

2013-09-23, 1392/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
Treatment of periodontitis and chronic periodontitis and the complications

**Public title**  
Treatment of gum disease

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
This study is a double-blind randomized clinical trial and is done in a full mouth design. Totally 44 patients to be surveyed in this study. The patient have periodontal pocket with 5 mm depth and more it also needs to be mentioned that these patients have Chronic periodontitis that have not answered to phase one and the periodontal pocket is left in them. It must be said that the age range is 35 and over it more over. These patients criteria is remaining periodontal pocket after doing phase one. More over to these facts: 1. The patients must be without systematic disease. 2. Pregnant patients are not to be taken part. 3. The patients must not use drugs or smoke. 4. The patients must not have used any antibiotic in a 6 month period. The patients go under SRP treatment for the 2nd time after clinical check-up and registering parameters like BOP / CAL / PPD / FMBS / FMPS and PI. If one the 50 patients FMPS is lower than 20% he/she gets radiated in the 1st 2nd and 7th days during 3 sessions in 3 days. In order to see that there is no dental plaque the patients are to be checked-up one week after doing SRP. Every patients left pocket gets radiated with Diode laser and EmunDo. The sensitive substance to light (photosensitizer) The day after check-up in the 1st 3rd and 7th days over a week. In goal group: all teeth go under PDT with Diode laser followed by EmunDo photosensitizer having 300 mw power in 10 seconds and 3 joule energy in 6 adjacent dental points. In beholder group all teeth including those that have periodontal pocket with the depth of 5 mm and more and without periodontal pocket go under SRP with physiologic serum and off laser. than the patients are to be re-studied and compared in one three and six month intervals.

**Age**  
From **35 years** old to **60 years** old

**Gender**  
Both

**Phase**  
0

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **44**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Office of Research Affairs (research assistant)

##### Street address

Tehran

##### City

Tehran

##### Postal code

#### Approval date

2012-11-11, 1391/08/21

#### Ethics committee reference number

91-04-97-20051-103312

## Health conditions studied

### 1

#### Description of health condition studied

Chronic periodontitis

#### ICD-10 code

K05.3

#### ICD-10 code description

Gingivitis and periodontal diseases

## Primary outcomes

### 1

#### Description

1. Bleeding on probing (BOP)

#### Timepoint

Scaling done before / after scaling a week / a month after

laser irradiation / Three months after laser irradiation /

Six months after laser irradiation

#### Method of measurement

Observed / measured probe

### 2

#### Description

Clinical attachment loss (CAL)

#### Timepoint

Scaling done before / after scaling a week / a month after

laser irradiation / Three months after laser irradiation /

Six months after laser irradiation

#### Method of measurement

Observed

### 3

#### Description

Plaque index (PI)

**Timepoint**  
Scaling done before / after scaling a week / a month after laser irradiation / Three months after laser irradiation / Six months after laser irradiation

**Method of measurement**  
Observed

## 4

**Description**  
Full mouth plaque score (FMPS)

**Timepoint**  
Scaling done before / after scaling a week / a month after laser irradiation / Three months after laser irradiation / Six months after laser irradiation

**Method of measurement**  
Observed

## 5

**Description**  
Full mouth bleeding score (FMBS)

**Timepoint**  
Scaling done before / after scaling a week / a month after laser irradiation / Three months after laser irradiation / Six months after laser irradiation

**Method of measurement**  
Observed

## 6

**Description**  
Periodontal probing depth (PPD)

**Timepoint**  
Scaling done before / after scaling a week / a month after laser irradiation / Three months after laser irradiation / Six months after laser irradiation

**Method of measurement**  
Observed / measured probe

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**  
The patient will be under SRP (Scaling and Root planing) treatment after a clinical check-up and registering the below parameters: 1. Bleeding on probing (BOP) 2. Clinical attachment loss (CAL) 3. Plaque index (PI) 4. Full mouth plaque score (FMPS) 5. Full mouth bleeding score (FMBS) 6. Periodontal probing depth (PPD) In order to see that there is no dental plaque. The patients are to be checked-up in the 1st 3rd and 7th days one week after SRP every single gets radiated in 3 sessions over 3 days that every radiation is in the 1st 3rd 7th days over a week in this research. We randomly split the patients into 2 groups called beholder and goal. The goal group: The patients continuously go under photodynamic

therapy with 810 nanometer Diode laser Having 300 mw power in 10 seconds and 3 joule energy in 6 adjacent dental points followed by EmuDo photosensitizer .

**Category**  
Placebo

## 2

**Description**  
The beholder group: The patients go under SRP treatment with physiology serum and off laser. the approved patients are to be reviewed and compared in one three and six month intervals.

**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**  
Department of Periodontology, Dental School, Tehran University of Medical Sciences

**Full name of responsible person**  
Omid Bagherpasand Tamijani

**Street address**  
Dental School, Tehran University of Medical Sciences, North Amir Abad Tst. Tehran

**City**  
Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**  
Laser Department, Dental School of Tehran University of Medical Sciences

**Full name of responsible person**  
Abas Monzavi

**Street address**  
Dental School, 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 Department, Dental School of Tehran 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**  
Dental School, Tehran University of Medical Sciences  
**Full name of responsible person**  
Omid Bagherpasand Tamijani  
**Position**  
Doctor of Dental Medicine  
**Other areas of specialty/work**  
**Street address**  
Dental School, Tehran University of Medical Sciences,  
North Amir Abad Tst. Tehran  
**City**  
Tehran  
**Postal code**  
**Phone**  
**Fax**  
**Email**  
omid.dds67@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Dental School, Tehran University of Medical Sciences  
**Full name of responsible person**  
Abbas Monzavi  
**Position**  
Associate professor  
**Other areas of specialty/work**  
**Street address**  
Dental School, Tehran University of Medical Sciences  
**City**  
Tehran  
**Postal code**  
**Phone**

**Fax**  
**Email**  
monzavia@sina.tums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Dental School, Tehran University of Medical Sciences  
**Full name of responsible person**  
Omid Bagherpasand Tamijani  
**Position**  
Doctor of Dental Medicine  
**Other areas of specialty/work**  
**Street address**  
Dental School, Tehran University of Medical Sciences,  
North Amir Abad Tst. Tehran  
**City**  
Tehran  
**Postal code**  
**Phone**  
**Fax**  
**Email**  
omid.dds67@gmail.com  
**Web page address**

## 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*