

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Assessment of the effect of photodynamic therapy on treatment of moderate-to-severe periodontitis

#### Protocol summary

##### Summary

In this single-blind clinical trial, 30 patients who had referred to Faculty of Dentistry, University of Babol will be selected based on inclusion criteria (having at least 20 teeth in the mouth, etc.) and exclusion criteria (pregnancy, etc.). The first 10 subjects form the first intervention group (Photo-dynamic Therapy), and the other 20 ones will be randomly and equally divided into the control group (under scaling/root planting (SRP) treatment) and the second intervention group (under a combination of Photo-dynamic Therapy and SRP). In the second intervention group, treatment processes of Photo-dynamic Therapy will be done immediately after SRP. The light-sensitive material used in the study (manufacturer: CMS Dental, Denmark) contains 10 milligrams per milliliter methylene Blue (16, 18, and 19) that will be directly applied into the periodontal pockets for at least 60 seconds. Then, using Photo-San system (manufactured by the same company) and by means of a 15-mm perio-tip located inside each periodontal pocket, all surfaces of the tooth are exposed for at least 30 seconds and the pocket is rinsed. Given the uniform distribution of light in this system, it will be possible to distribute it throughout the periodontal pockets. Primary outcomes including pocket probing depth (PPD) (in millimeter per six areas of each tooth), bleeding on probing (BOP), and clinical attachment level (CAL) will be measured. All measurements will be performed by another clinician one, three, six, and twelfth weeks after the start of the trial.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201512251760N44**

Registration date: **2016-02-23, 1394/12/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-02-23, 1394/12/04

##### Registrant information

###### Name

Nargess Gholizadeh Pasha

###### Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-06-21, 1395/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of the effect of photodynamic therapy on treatment of moderate-to-severe periodontitis

##### Public title

Assessment of the effect of photodynamic therapy on

treatment of moderate-to-severe periodontitis

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: age older than 18 years old; having at least 20 teeth in the mouth; having at least one area with probing depth of four millimeters in at least two quadrants of the mouth (with bleeding on probing light); the plaque index, less than thirty percent. Exclusion criteria: pregnancy; received scaling and root planing procedures or antibiotic therapy in the last six months; systemic disease affecting periodontal health; smoking.

### **Age**

From **18 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **30**

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

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Groups based on all parameters (including PPD, CAL, BOP and plaque index) and with regard to the inclusion and exclusion criteria will be mentioned in the same building. All calculations weeks, third, sixth and twelfth after treatment by a clinicians will no longer do. Blindness study done.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Babol University of Medical sciences

##### **Street address**

Babol University of Medical Sciences, Ganjafroz Avenu

##### **City**

Babol

##### **Postal code**

##### **Approval date**

2015-12-06, 1394/09/15

##### **Ethics committee reference number**

MUBABOI.REC.1394.206

## **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**

A week after the start of the study and at weeks three, six and twelve after treatment

#### **Method of measurement**

Clinical

### 2

#### **Description**

Clinical attachment level

#### **Timepoint**

A week after the start of the study and at weeks three, six and twelve after treatment

#### **Method of measurement**

Clinical

### 3

#### **Description**

Bleeding on probing(BOP)

#### **Timepoint**

A week after the start of the study and at weeks three, six and twelve after treatment

#### **Method of measurement**

Clinical

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control groups: This group will be under scaling/root planting (SRP) treatment.

#### **Category**

N/A

### 2

#### **Description**

Intervention group 1: In this group, Photo-dynamic Therapy will be used.

**Category**

Treatment - Other

**3****Description**

Intervention group 2: A combination of Photodynamic Therapy and SRP will be used in this group. Treatment processes of Photodynamic Therapy will be done immediately after SRP. The light-sensitive material used in the study (manufacturer: CMS Dental, Denmark) contains 10 milligrams per milliliter methylene Blue (16, 18, and 19) that will be directly applied inside the periodontal pockets for at least 60 seconds. Then, using PhotoSan system (manufactured by the same company) and by means of a 15-mm perio-tip located inside each periodontal pocket, all surfaces of the tooth are exposed for at least 30 seconds and the pocket is rinsed. Given the uniform distribution of light in this system, it will be possible to distribute it throughout the periodontal pockets.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Dental colleges of Babol

**Full name of responsible person**

Dr. Ida Mirzaee

**Street address**

Dental College, Babol University of Medical Sciences, Ganjafrooz Avenue

**City**

Babol

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for Research, Babol University of Medical Sciences

**Full name of responsible person**

Dr. Ali Bijani

**Street address**

Ganjafrooz Avenue, Babol University of Medical sciences

**City**

Babol

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for Research, Babol 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 College of Babol

**Full name of responsible person**

Dr. Ida Mirzaee

**Position**

Post graduate student of periodontology

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Dental College of Babol

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**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*