Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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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

MUBABOl.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
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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