

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Study of the clinical and microbiologic effects of 940 nm Diode laser as an adjunct to scaling and root planing in treatment of Chronic periodontitis

#### Protocol summary

##### Study aim

This study was undertaken to evaluate the effect of 940-nm diode laser on clinical parameters and microbial load in patients with chronic periodontitis.

##### Design

Randomized, single blinded, clinical trial

##### Settings and conduct

This study will be carried out on patients referred to Faculty of Dentistry, Shahed University, Tehran. Full-mouth SRP will be done with an ultrasonic device. Oral hygiene instructions, consisting of correct brushing technique and correct use of dental floss will be given to each patients. One week after completion of SRP in the test group after simple randomization with random number, 940-nm diode laser beams will be applied. One tooth from each quadrant will be selected for evaluation of clinical and microbiological parameters. Sterile paper cones will be placed in the deepest area of the pocket and after 20 seconds will be immediately placed in tubes for transferring to the laboratory. All the four samples of each patient will be sent to the laboratory. Real-time PCR will be used to determine pathogen counts.

##### Participants/inclusion and exclusion criteria

Inclusion criteria: -Subjects had moderate-to-severe chronic periodontitis. -At least one pocket, measuring 4–6 mm in depth, and bleeding on probing in each quadrant. -Systemic health. -Lack of active root infection or teeth caries. Exclusion criteria: -Lack of compliance. -Periodontal pockets deeper than 10 mm, and severe luxation (third degree). -Antibiotics intake during the research and in previous three months. -Smoking

##### Intervention groups

1. Scaling root planing as conventional treatment
2. Scaling root planing + 940 nm diode laser application

##### Main outcome variables

Papillary bleeding index (PBI), probing pocket depth (PPD), clinical attachment level (CAL), modified gingival index (MGI) and margin level (ML), and microbial load

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161216031432N2**

Registration date: **2018-04-02, 1397/01/13**

Registration timing: **retrospective**

Last update: **2018-04-02, 1397/01/13**

Update count: **0**

##### Registration date

2018-04-02, 1397/01/13

##### Registrant information

##### Name

zahra zohri

##### Name of organization / entity

Shahed University, Tehran, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8895 9210

##### Email address

z.zohri@shahed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

no fund

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2018-02-04, 1396/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Study of the clinical and microbiologic effects of 940 nm Diode laser as an adjunct to scaling and root planing in treatment of Chronic periodontitis

## Public title

Laser in periodontitis treatment

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Moderate to severe chronic generalized periodontitis, presence of one pocket measuring 4–6 mm in depth and bleeding on probing in all the 4 quadrants Systemic health

### Exclusion criteria:

Presence of radicular infection or active caries Systemic diseases

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **22**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization of subjects with random number table

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Single blind; participants

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahed University of Medical Sciences

##### Street address

Shahed University, Tehran, Iran. N71, Italia Str, Vesal Ave, Tehran ,Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

3319118651

##### Approval date

2017-02-28, 1395/12/10

##### Ethics committee reference number

IR.Shahed.REC.1395.220

## Health conditions studied

### 1

#### Description of health condition studied

Chronic periodontitis

#### ICD-10 code

K05.3

#### ICD-10 code description

Chronic pericoronitis Periodontitis: NOS complex simplex

## Primary outcomes

### 1

#### Description

Pocket Probing Depth

#### Timepoint

before treatment,1 month and 3 month after treatment

#### Method of measurement

The distance between the gingival margin and the pocket base, which will be measured at 6 points of each tooth (mesiobuccal, buccal, distobuccal, distolingual, lingual and mesiolingual) with the use of a Williams graduated probe. The mean probing depth at each site will be registered as the probing depth in that area.

### 2

#### Description

Clinical Attachment Level

#### Timepoint

before treatment,1 month and 3 month after treatment

#### Method of measurement

Williams probe

### 3

#### Description

Gingival Level

#### Timepoint

before treatment,1 month and 3 month after treatment

#### Method of measurement

Williams probe

### 4

#### Description

Modified Gingival Index

#### Timepoint

before treatment,1 month and 3 month after treatment

#### Method of measurement

Observation

## 5

### **Description**

Papillary Bleeding Index

### **Timepoint**

before treatment,1 month and 3 month after treatment

### **Method of measurement**

Periodontal probe and observation

## 6

### **Description**

Porphyromonas gingivalis

### **Timepoint**

before treatment,1 month and 3 month after treatment

### **Method of measurement**

Real time polymerase chain reaction

## 7

### **Description**

Tannerella forsythia

### **Timepoint**

before treatment,1 month and 3 month after treatment

### **Method of measurement**

Real time polymerase chain reaction

## 8

### **Description**

Treponema denticola

### **Timepoint**

before treatment,1 month and 3 month after treatment

### **Method of measurement**

Real time polymerase chain reaction

## **Secondary outcomes**

### 1

#### **Description**

-

#### **Timepoint**

-

#### **Method of measurement**

-

## **Intervention groups**

### 1

#### **Description**

The control group: The treatment consists of scaling with an ultrasonic device and oral hygiene instructions, including how to brush correctly and use dental floss.

#### **Category**

Treatment - Devices

### 2

#### **Description**

The intervention group: Scaling will be carried out with the use of an ultrasonic device in association with oral

hygiene instructions, including correct brushing and use of dental floss. One week after scaling and root planing, 940-nm diode laser beams w

#### **Category**

Treatment - Devices

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

School of Dentistry of Shahed University

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

Zahra Zohri (post graduate)

##### **Street address**

Shahed University, Persian gulf highway

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

3319118651

##### **Phone**

+98 21 4445 9468

##### **Email**

z.zohri@shahed.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

No sponser

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

Zahra Zohri

##### **Street address**

Shahed University, Persian gulf highway

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

3319118651

##### **Phone**

+98 21 4445 9468

##### **Email**

z.zohri@shahed.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

No sponser

#### **Proportion provided by this source**

100

#### **Public or private sector**

Private

#### **Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

School of Dentistry of Shahed University

**Full name of responsible person**

Zahra Zohri

**Position**

Post graduate

**Latest degree**

Medical doctor

**Other areas of specialty/work****Street address**

Shahed University, Persian gulf highway

**City**

Tehran

**Province**

Tehran

**Postal code**

3319118651

**Phone**

+98 21 8895 9210

**Fax****Email**

z.zohri@shahed.ac.ir

**Web page address**

http://shahed.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

School of Dentistry of Shahed University

**Full name of responsible person**

Zahra Zohri

**Position**

Postgraduate

**Latest degree**

Medical doctor

**Other areas of specialty/work****Street address**

N71, Italia Str, Vesal Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

3319118651

**Phone**

+98 21 8895 9210

**Fax****Email**

z.zohri@shahed.ac.ir

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

School of Dentistry of Shahed University

**Full name of responsible person**

Zahra Zohri

**Position**

Postgraduate

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

N71, Italia Str, Vesal Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

3319118651

**Phone**

+98 21 8895 9210

**Fax****Email**

z.zohri@shahed.ac.ir

**Web page address**

http://shahed.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data after removal of private information will release via article publication.

**When the data will become available and for how long**

6 months after publication.

**To whom data/document is available**

Students and professors

**Under which criteria data/document could be used**

By written consent of investigators.

**From where data/document is obtainable**

Dr. Zohri

**What processes are involved for a request to access data/document**

email online application of the assay.

**Comments**