

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of 940-nm Diode Laser Effectiveness on Pocket Depth, Clinical Attachment Level and Bleeding on Probing in Chronic Periodontitis

#### Protocol summary

##### Study aim

We intend to conduct this study with the laser treatment model of the RWTH University of Aachen, Germany. If we get favorable results, we will propose a more effective solution than conventional non-surgical treatment methods (SRP and antibiotic therapy).

##### Design

Randomized, parallel-group trial with blinded outcome assessment. Randomization for choosing left or right was conducted by tossing a coin.

##### Settings and conduct

Patients referring to the Anzali campus dental school clinic and a specialized private practice in Rasht city in 1401-1402 are studied depending on the number calculated in the statistical survey. The person responsible for measuring clinical parameters and patients will not be aware of the laser-treated side.

##### Participants/Inclusion and exclusion criteria

1. Not receiving any periodontal treatment in the last 12 months
2. Not taking any type of antibiotic, anti-inflammatory, or oral contraceptive drugs during the last 3 months
3. Absence of any systemic disease that affects the periodontal treatment process such as uncontrolled diabetes
4. Absence of pregnancy
5. Not using any type of tobacco or drug addiction
6. No need for antibiotic prophylaxis
7. Having at least 1 point with a probe depth of more than 3 mm in each studied part

##### Intervention groups

The number of 44 oral segments (first premolar, second premolar, and molar teeth of each quadrant) in 12 patients are equally and randomly placed in two treatment groups: Scaling & Root Planing (SRP) and Scaling & Root Planing + Laser (SRP+L).

##### Main outcome variables

Diode laser with wavelengths between 655 and 980 nm can accelerate wound healing and increase angiogenesis and growth factor release. If the positive effect of laser in improving periodontal parameters is determined, this method can be used as a routine method in non-surgical

treatments.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221210056769N1**

Registration date: **2022-12-13, 1401/09/22**

Registration timing: **prospective**

Last update: **2022-12-13, 1401/09/22**

Update count: **0**

##### Registration date

2022-12-13, 1401/09/22

##### Registrant information

##### Name

Seyed Ali Seyed-Monir

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3372 1607

##### Email address

mihandoust.sanaz3@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-04-21, 1402/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of 940-nm Diode Laser Effectiveness on Pocket Depth, Clinical Attachment Level and Bleeding on Probing in Chronic Periodontitis

### Public title

The Effect of 940-nm Diode on Periodontal Conditions

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients receiving no periodontal treatments during the last 12 months  
No antibiotic consumption during the last 3 months  
Absence of any systematic disease (i.e. diabetes) affecting the process of periodontal treatment  
No anti-inflammatory drug consumption during the last 3 months  
No pregnancy  
No oral contraceptive pills consumption  
No smoking or drug addiction  
No need for antibiotic prophylaxis

#### Exclusion criteria:

Discontinuing the treatment procedure by the patient  
Becoming affected by a disease that requires medical therapy during the investigation period

### Age

From **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **12**

More than 1 sample in each individual

Number of samples in each individual: **4**

The number of 44 oral segments (first premolar, second premolar, and molar teeth of each quadrant) in 12 patients were equally and randomly placed in two treatment groups: Scaling & Root Planing (SRP) and Scaling & Root Planing + Laser (SRP+L).

### Randomization (investigator's opinion)

Randomized

### Randomization description

In the first session, supragingival scaling of the whole mouth and hygiene education is performed, and then clinical parameters including pocket depth (PD), clinical attachment loss (CAL), and bleeding on probing (BOP) are measured in 6 points of each tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual and distolingual) and recorded in the corresponding form. It should be noted that the accuracy of the examiner's assessment will be checked and confirmed in several test sessions and cases under the supervision of a periodontist. Then, subgingival scaling and root planing (SRP) is performed under local anesthesia by a periodontist with a valid laser fellowship. Subsequently,

one of the two left or right sides is chosen randomly by tossing a coin for the adjunctive laser treatment, and by the same periodontist undergoes laser therapy with the protocol approved by the Laser Center of RWTH University of Aachen, Germany. On the SRP side, the tip of the laser fiber is moved without being activated, similar to the method performed on the SRP+L side, so the patient does not know which side has undergone laser therapy. A week later, laser therapy is repeated without performing SRP according to the above method. It should be noted that the person responsible for measuring clinical parameters will not be aware of the laser-treated side.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

On the SRP side, the tip of the laser fiber is moved without being activated, similar to the method performed on the SRP+L side, so the patient does not know which side has undergone laser therapy. A week later, laser therapy is repeated without performing SRP according to the above method. It should be noted that the person responsible for measuring clinical parameters will not be aware of the laser-treated side.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Guilan University of Medical Sciences

##### Street address

Dentistry Faculty, Guilan University of Medical Sciences, Fuman-Saravan Road

##### City

Rasht

##### Province

Guilan

##### Postal code

4194173774

#### Approval date

2017-12-16, 1396/09/25

#### Ethics committee reference number

IR.GUMS.REC.1396.383

## 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

Comparative assessment of periodontal pocket depth after treatment in the case and control groups

#### Timepoint

3 months

#### Method of measurement

Using a scaled periodontal probe, the distance between the gingival wall and the tooth surface from the gingival margin to the uppermost part of the junctional epithelium is measured and recorded.

### 2

#### Description

Comparative assessment of clinical attachment loss (CAL) after treatment in the case and control groups

#### Timepoint

3 months

#### Method of measurement

Using a scaled periodontal probe, the distance between the border of the enamel and cementum (Cemento-Enamel Junction) to the depth of the pocket is measured and recorded.

### 3

#### Description

Comparative assessment of bleeding on probing (BOP) after treatment in the case and control groups

#### Timepoint

3 months

#### Method of measurement

Checking the presence or absence of blood leakage 30 seconds after probing the periodontal pocket

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: scaling and root planing (SRP) of the selected teeth

#### Category

Treatment - Devices

### 2

#### Description

#### Category

empty

### 3

#### Description

Intervention group: 980nm diode laser therapy of the selected teeth following the scaling and root planing (SRP)

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Guilan university of medical sciences - Anzali international campus

##### Full name of responsible person

Dr. Seyed Ebrahim Seyed-Monir

##### Street address

Gilan University of Medical Sciences International Campus Faculty, 30 meters Blvd., Bandar Anzali

##### City

Anzali

##### Province

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##### Postal code

43146-37758

##### Phone

+98 13 4455 3185

##### Fax

##### Email

ib@gums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Specialized dental office

##### Full name of responsible person

Dr. Seyed Ebrahim Seyed-Monir

##### Street address

specialized dental office of Dr. Seyed ebrahim Seyed-Monir, 3rd floor, Naderi Building, Saadi St., Gulsar

##### City

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##### Province

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##### Postal code

41356-33366

##### Phone

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##### Email

seyedmonir.ali13@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

**Full name of responsible person**

Ms. Amani

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Gilan University of Medical Sciences International  
Campus Faculty, 30 meters Blvd., Bandar Anzali

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**Email**

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

No

**Title of funding source**

Personal by the researcher

**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**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Ebrahim Seyed-Monir

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Periodontist

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

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**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to

make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to

make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available