

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of two methods of scaling and root planning (SRP) and low level laser therapy in treatment of patients with moderate to severe chronic periodontitis

#### Protocol summary

##### Study aim

Comparison of the effect of two methods of scaling and root planning (SRP) and low level laser therapy in treatment of patients with moderate to severe chronic periodontitis

##### Design

Randomization is done by random numbers table. The sample size is 36 people. This clinical trial has 3 groups. A control group and two intervention groups. Double blind study with parallel groups.

##### Settings and conduct

This study is performed in Birjand Dental School. Patients do not know the type of treatment they receive. Variables evaluators and data analyzers are unaware of group of each sample.

##### Participants/Inclusion and exclusion criteria

Entry conditions: - Having at least 20 teeth in the mouth ; - Having at least 1 area with a pocket depth of 4 mm and more in at least 2 quadrants of the mouth, with bleeding in the mild probing; - Having an index plaque less than 30%; - availability during the research process and the signing of the written agreement. Exit conditions: - Pregnancy; - smoking; -The presence of systemic disease that affects the periodontal condition; - Receiving scaling and root planning or antibiotic therapy in the last 6 months.

##### Intervention groups

Group 1: Low Level Laser Therapy Group 2: Scaling and root planing Group 3: Scaling and root planing with low level laser therapy

##### Main outcome variables

1- Clinical Attachment Level (CAL) : The distance between the CEJ and the gingival groove in millimeters 2- bleeding on probing (BOP): presence or absence of bleeding 30 seconds after mild probing in the buccal and lingual area of the tooth 3- probing pocket depth(PPD):the distance between the free gingiva to the

end of gingival groove in millimeters 4- Percentage of BOP Total Oral Area

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180624040231N1**

Registration date: **2018-09-24, 1397/07/02**

Registration timing: **retrospective**

Last update: **2018-09-24, 1397/07/02**

Update count: **0**

##### Registration date

2018-09-24, 1397/07/02

##### Registrant information

##### Name

Fateme Ghanei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3502 7573

##### Email address

F.ghanei@bums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2018-09-21, 1397/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of two methods of scaling and root planning (SRP) and low level laser therapy in treatment of patients with moderate to severe chronic periodontitis

**Public title**  
Comparison of the effect of two methods of dental scaling in patients with gum disease

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having at least 20 teeth in the mouth Having at least 1 area with a pocket depth of 4 mm and more in at least 2 quadrants of the mouth, with bleeding in the mild probing Having an index plaque less than 30% availability during the research process and the signing of the written agreement  
**Exclusion criteria:**  
Pregnancy smoking The presence of systemic disease that affects the periodontal condition Receiving scaling and root planning or antibiotic therapy in the last 6 months

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **36**

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

**Randomization description**  
Random numbers tables are used for randomization.

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

**Blinding description**  
Patients participating are not aware of the type of treatment they receive. Also data analyzer and the variables evaluator do not know about groups. A group of patients receive laser therapy after routine scaling. For a group who receive laser therapy alone, after study a scaling will be done. For a control group, who receive scaling alone. As a placebo, a laser's periotype is placed in gingival sulcus, without the laser being turned on.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Birjand University of Medical Science

##### Street address

Ghaffari Blv. , Birjand University of Medical Science

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717803077

#### Approval date

2018-05-13, 1397/02/23

#### Ethics committee reference number

IR.BUMS.REC.1397.009

## Health conditions studied

### 1

#### Description of health condition studied

chronic periodontitis

#### ICD-10 code

1

#### ICD-10 code description

Certain infectious and parasitic diseases

## Primary outcomes

### 1

#### Description

Clinical Attachment Level (CAL) : The distance between the CEJ and the gingival groove in millimeters

#### Timepoint

At the beginning of the study, 3, 6 and 12 weeks after the intervention

#### Method of measurement

by periodontal probes

### 2

#### Description

bleeding on probing (BOP): presence or absence of bleeding 30 seconds after mild probing in the buccal and lingual area of the tooth

#### Timepoint

At the beginning of the study, 3, 6 and 12 weeks after the intervention

#### Method of measurement

Presence or absence of bleeding and seeing it by clinician

### 3

#### **Description**

probing pocket depth(PPD):the distance between the free gingiva to the end of gingival groove in millimeters

#### **Timepoint**

At the beginning of the study, 3, 6 and 12 weeks after the intervention

#### **Method of measurement**

by periodontal probes

### 4

#### **Description**

Percentage of BOP Total Oral Area

#### **Timepoint**

At the beginning of the study, 3, 6 and 12 weeks after the intervention

#### **Method of measurement**

Presence or absence of bleeding and seeing it by clinician and Counting the percentage of bleeding areas

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control group: scaling and root planing

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group: Using a laser diode system at a wavelength of 980 nm and a power of 0.5 watts, a pulse frequency of 15 Hz, an energy of 1.2 j/mm<sup>2</sup> in a pulsed state in each periodontal pocket using a 15 mm periotip for at least 30 seconds in periodontal pocket of each tooth

#### **Category**

Treatment - Other

### 3

#### **Description**

Intervention group: scaling and root planing followed by Using a laser diode system at a wavelength of 980 nm and a power of 0.5 watts, a pulse frequency of 15 Hz, an energy of 1.2 j/mm<sup>2</sup> in a pulsed state in each periodontal pocket using a 15 mm periotip for at least 30 seconds in periodontal pocket of each tooth

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Dental Clinic Dependent on Birjand Dental School

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

Saeid Asadollahi

##### **Street address**

Emam Reza hospital - Taleghani avenue

##### **City**

Birjand

##### **Province**

South Khorasan

##### **Postal code**

9717853577

##### **Phone**

+98 56 3223 3690

##### **Email**

ghanei\_fateme@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Birjand University of Medical Sciences

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

Ebrahim Miri Moghaddam

##### **Street address**

Birjand university of medical science , Ghaffari blv.

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##### **Email**

public-r@bums.ac.ir

#### **Grant name**

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

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

Yes

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

Birjand University of Medical Sciences

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

100

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

Public

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

Domestic

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## Person responsible for general inquiries

sma.tabatabaei@gmail.com

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Fateme Ghanei

**Position**

dentistry student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Ali Tabatabaei

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Fateme Ghanei

**Position**

dentistry student

**Latest degree**

Medical doctor

**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**

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

**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