

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Clinical efficacy of 940-nm diode laser in the treatment of persistent and recurrent pockets in the periodontal maintenance phase

Protocol summary

Evaluation of PI PPD, CAL, BI indices

Study aim

Achieving a suitable method for the treatment of stable and recurrent pockets in the periodontal maintenance phase using less invasive methods and avoiding surgery

Design

Double-blinded split-mouth randomized clinical trial

Settings and conduct

Diode laser (Biolase Inc, India) specifications are as follows: wavelength: 940 nm; power: 1 w; 300 micrometer symbol uninitiated fibers; continuous radiation mode and energy level: 80J / S. The laser fibers then are inserted into the pockets in such a way that they are in contact with the soft tissue wall of the pockets and parallel to the root surface and then move to the apical surface through a horizontal sweeping motion while remaining in contact with the soft tissue wall of the pockets. The control group undergo treatment using placebo laser and adjacent areas of the studied areas are treated with the treatment protocol used for the same area. The studied areas do not receive any local anesthesia and each patient is given oral health training at the same treatment session and will examine to re-measure the indices in the first and third months after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria included no systemic diseases, no smoking, no pregnancy and breastfeeding, no regular use of nonsteroidal anti-inflammatory drugs and antibiotics in the last three months, no history of any periodontal treatment for at least the last 3 months, and at least 3 teeth in two different quadrants with 4-7 mm PPD and positive BI. Exclusion criteria also included non-co-working patients, and patients with $PI \geq 1$.

Intervention groups

After collecting the indices, the areas in different quadrants with 4-7 mm PPD and positive BI are randomly divided into experimental (SRP + Laser) and control groups (SRP alone) by throwing coins.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201226049831N1**

Registration date: **2021-01-01, 1399/10/12**

Registration timing: **retrospective**

Last update: **2021-01-01, 1399/10/12**

Update count: **0**

Registration date

2021-01-01, 1399/10/12

Registrant information

Name

Zahra Alizadeh Tabari

Name of organization / entity

Department of periodontics, International Campus,
School of Dentistry, Tehran University of Medical

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-25, 1396/02/05

Expected recruitment end date

2018-04-30, 1397/02/10

Actual recruitment start date

2017-04-25, 1396/02/05

Actual recruitment end date

2018-04-30, 1397/02/10
Trial completion date
2018-06-05, 1397/03/15

Scientific title

Clinical efficacy of 940-nm diode laser in the treatment of persistent and recurrent pockets in the periodontal maintenance phase

Public title

Laser in periodontal maintenance phase

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

no systemic diseases, no smoking, no pregnancy and breastfeeding, no regular use of nonsteroidal anti-inflammatory drugs and antibiotics in the last three months, no history of any periodontal treatment for at least the last 3 months, and at least 3 teeth in two different quadrants with 4-7 mm PPD and positive BI.

Exclusion criteria:

included non-co-working patients, and patients with $PI \geq 1$.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

experimental (SRP + Laser) and control groups (SRP alone)

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple After collecting the indices, the areas in different quadrants with 4-7 mm PPD and positive BI are randomly divided into experimental (SRP + Laser) and control groups (SRP alone) by throwing coins. The both groups are then matched for PI, based on the silness-loe plaque index and when treatment of the first area was determined, the next area was treated using another protocol.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the operator are not aware of the laser or placebo, and the third person makes the laser adjustments

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Bahonar

City

Qazvin

Province

Qazvin

Postal code

34157-59811

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.QUMS.REC.1395.310

Health conditions studied

1

Description of health condition studied

Periodontal disease

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

Periodontal pocket depth(PPD), bleeding index(BI), clinical attachment level(CAL)

Timepoint

Before intervention and 1 and 3 months after intervention

Method of measurement

PPD is measured in millimeters from the free gingival margin to the base of the periodontal pockets using a manual periodontal probe. BI was defined as the presence or absence of bleeding 30 seconds after probing (\pm). CAL is also defined as the distance (mm) from cemento-enamel junction (CEJ) to the bottom of the pockets.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: all oral areas are treated with SRP using ultrasonic pens. Laser is then performed on the experimental group to remove the inner layer of the pockets and thus reduce the microbial load using the diode laser according to the manufacturer's instructions.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Qazvin University of Medical Sciences

Full name of responsible person

Zahra Alizadeh Tabari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Alizadeh Tabari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Zahra Alizadeh Tabari

Position

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Latest degree

Specialist

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Person responsible for updating data

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

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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

Not applicable

Title and more details about the data/document

The charts are in periodontics department of Qazvin dental school

When the data will become available and for how long

Starting 2 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Access to view and review data

From where data/document is obtainable

By sending email to drz.alizadeh@gmail.com

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

This process may last about 1 month

Comments