

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of non-surgical periodontal treatment with diode laser or photodynamic therapy with Emundo mixture on clinical and microbiological indices in patients with chronic periodontitis

Protocol summary

Summary

Objectives: The purpose of present study is to evaluate the impact of non-surgical laser therapy and photodynamic therapy on chronic periodontitis. **Design:** In this randomized clinical trial, twenty patients with chronic periodontitis were selected among the patients referring to Isfahan University of medical sciences by convenience sampling. **Setting and Conduct:** Mechanical debridement was accomplished for the whole mouth. Applying a split-mouth design, each quadrant was randomly treated with one of the therapeutic interventions. This randomization was done with table of randomization numbers. **Participants:** the patients should be systemically healthy and no smoker. **Interventions:** therapeutic interventions including 1- mechanical debridement alone, 2- mechanical debridement +laser therapy, or 3- mechanical debridement + photodynamic therapy were accomplished in 2 sessions within 2 weeks. **Variables:** The clinical indices including, pocket probing depth, clinical attachment level, papillary bleeding index and plaque index were measured at baseline, 6 weeks and 3 months after treatment. Microbiological samples were taken and evaluated at baseline and 3-month follow-up. Triple blinding during the study procedure was performed for patient (by placebo treatment in other quadrants), researcher and data monitoring committee (by unawareness of intervention process).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021021029N1**

Registration date: **2015-04-15, 1394/01/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-15, 1394/01/26

Registrant information

Name

Sima Kiani

Name of organization / entity

Department of Periodontology, dental school, Isfahan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Faculty of Dentistry, Isfahan University of Medical Sciences.

Expected recruitment start date

2014-01-31, 1392/11/11

Expected recruitment end date

2014-02-28, 1392/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of non-surgical periodontal treatment with diode laser or photodynamic therapy with Emundo mixture on clinical and microbiological indices in patients with chronic periodontitis

Public title

The effect of laser therapy on chronic gingival disease

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 1) Age $\geq$ 18, 2) Systemically healthy, 3) Remaining teeth $\geq$ 20, 4) Presence of three or more quadrants of mouth, each containing at least three sites with periodontal pocket depth (PPD) of 4-7 mm and clinical attachment level (CAL) of 2 mm or greater, 5) Signed informed consent form exclusion criteria: 1) Smoking or alcoholism, 2) Pregnancy or lactating, 3) Consuming antimicrobial drugs (i.e. antibiotics) in the last 2 months, and 4) History of periodontal surgery in the last year

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan university of medical sciences, Hezarjerib avenues, Isfahan

City

Isfahan

Postal code

81746 -73461

Approval date

2015-02-23, 1393/12/04

Ethics committee reference number

393386

Health conditions studied**1****Description of health condition studied**

chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic inflammatory disease of supporting tooth structure

Primary outcomes**1****Description**

pocket probing depth

Timepoint

Before Treatment, one month and 3 months after intervention

Method of measurement

probing with periodontal probe

Secondary outcomes**1****Description**

clinical attachment level

Timepoint

Before Treatment , one month and 3 months after intervention

Method of measurement

probing with periodontal probe

Intervention groups**1****Description**

intervention 3: control group: with laser device while it is off as placebo and photodynamic mixture while its syringe is blunt

Category

Placebo

2**Description**

intervention1: laser therapy with Diode laser with a wavelength of 810 (@Fox, A.R.C. laser GmbH, Germany)

Category

Treatment - Other

3**Description**

intervention 3: photodynamic therapy with Diode laser with a wave length of 810 and applying ® Emundo mixture (® Emundo, A.R.C. laser GmbH, Germany) as photosensitizer

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan University of Medical Sciences, School of Dentistry

Full name of responsible person**Street address****City**

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Dental school of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Omid Savabi

Street address

Research vice chancellor, Isfahan Dental School, Isfahan University of Medical Sciences, Hezarjerib Avenue, Isfahan

City

Isfahan

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, Dental school of Isfahan 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**

Isfahan Faculty of Dentistry

Full name of responsible person

Dr. Omid Savabi

Position

Proficiency of Prosthesis - Professor

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Position**Other areas of specialty/work****Street address****City****Postal code****Phone**

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Fax**Email**

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Web page address**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