

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of photodynamic therapy in improvement of periodontal parameters in chronic periodontitis patients

Protocol summary

Study aim

Investigating the added effect of photodynamic therapy on periodontal clinical indicators as a combined method with scaling root planing

Design

Split mouth clinical trial, with the intervention group the quadrants of one side of the mouth and control group quadrants on the opposite side in a patient with chronic periodontitis with pockets with a depth of 4-7mm, with parallel groups, double blinded, randomized by a table of random numbers and phase 3 It is performed on 35 patients.

Settings and conduct

In the investigation of the additional effect of photodynamic therapy with nanocurcumin using the split mouth method in patients who refer to the periodontology department of Mashhad Faculty of Dentistry, after scaling and root planing of the teeth, inject photosensitizer of nanocurcumin into the pockets on the intervention side and irradiate the buccal and lingual teeth continuously for 60 seconds with diode light. In the control group, after the injection of a neutral solution without activating the laser, we do the same as the intervention group. The second visit is 1 week later and all previous treatments are repeated. Periodontal parameters are measured before treatment, 1, 3 and 6 months after treatment. This study is double-blinded.

Participants/Inclusion and exclusion criteria

The criteria for entering: chronic periodontitis with pockets with a depth of 4-7mm in each quadrant and having optimal systemic health

Intervention groups

after scaling, inject nanocurcumin into the pockets on the intervention side and irradiate the buccal and lingual teeth continuously for 60 seconds with diode light. In the control group, after the injection of a neutral solution without activating the laser, we do the same as the intervention group.

Main outcome variables

Pocket depth: Plaque index: Bleeding index: Attachment level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231112060032N1**

Registration date: **2023-12-20, 1402/09/29**

Registration timing: **prospective**

Last update: **2023-12-20, 1402/09/29**

Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

Afsaneh Kouhi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 83 3427 4365

Email address

kouhia971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of photodynamic therapy in improvement of periodontal parameters in chronic periodontitis patients

Public title

Effect of photodynamic therapy on chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic periodontitis patients who have pockets with a depth of 4-7 mm in each quadrant and optimal systemic health.

Exclusion criteria:

Patients who have less than 16 teeth or partial or fixed dentures. Patients who have teeth with grade 3 laxity. Patients who have pockets deeper than 7mm. People who have taken antibiotics in the last 6 months. People who are pregnant or breastfeeding. People who smoke. Patients who do not want to cooperate.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **35**

More than 1 sample in each individual

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

In each person, the mouth is divided into 4 quadrants, each quadrant providing one sample.

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block method is used for randomization. According to the table of random numbers, if the number is even, it will be placed in block A and the next person will be placed in block B and if the number is odd, it will be placed in block B and the next number will automatically be placed in block A. In this study, the control groups are the right and left side of the participants' mouths. After the random assignment and before the treatment, a closed envelope is given to the performer so based on that, he knows which side to apply the laser on and which side to apply the laser off.

Blinding (investigator's opinion)

Double blinded

Blinding description

The principal investigator who applies the laser knows whether the laser is on or off and cannot be blind. The participants are blinded by wearing glasses and setting the device in such a way that the laser will be applied and the injection of placebo substance on the control

side and curcumin injection on the intervention side. The evaluator is blinded by not knowing about the treatment and control group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

The beginning of Vakil Abad Blvd, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2023-11-07, 1402/08/16

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1402.066

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**

Clinical depth of probing

Timepoint

Pocket depth was measured at the beginning of the study, 1, 3 and 6 months after treatment.

Method of measurement

Clinical measurements are performed at 6 points around the teeth using William's standard periodontal probe.

2**Description**

clinical attachment level

Timepoint

Pocket depth was measured at the beginning of the study, 1, 3 and 6 months after treatment.

Method of measurement

Clinical measurements are performed at 6 points around the teeth using William's standard periodontal probe.

3

Description

Bleeding on probing

Timepoint

Pocket depth was measured at the beginning of the study, 1, 3 and 6 months after treatment.

Method of measurement

Clinical measurements are performed at 6 points around the teeth using William's standard periodontal probe and Animo & Bay sulcus bleeding index.

4

Description

Plaque Index

Timepoint

Pocket depth was measured at the beginning of the study, 1, 3 and 6 months after treatment.

Method of measurement

Clinical measurements are performed at 6 points around the teeth using William's standard periodontal probe and Silness & Loe Plaque index.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The study is designed as a split-mouth (treatment with or without photodynamic therapy is randomly performed in each half).In treatment protocol in the first visit, the quadrants are equally divided into right and left sides, one side is performed as an intervention group (SRP and photodynamic therapy).After supra and subgingival scaling and whole mouth brossage, we inject photosensitizing solution Nano-Curcumin (N-CUR) (Sina Curcumin, Exir Nano sina, Tehran, Iran) which is dissolved in distilled water and has a concentration of 5g/l into the periodontal pockets on the test side. After 1 minute, remove the excess solution with a paper cone.After placing a piece of aluminum foil with a hollow 1cm*1cm square in the middle on the tooth, irradiate and activate the remaining solution in the buccal and palatal (lingual) tooth for 60 seconds non continuously (between three intervals of 20 seconds, two intervals of 60 seconds stop) with diode light (LED), 1200MV/CM2 (Woodpecker, X-cure, Guilin, China) that emits blue light with a spectrum of 515-385 nm and a central wavelength of 450 nm. The second visit is 1 week later and all previous treatments are repeated.

Category

Treatment - Devices

2

Description

Control group: The study is designed as a split-mouth (treatment with or without photodynamic therapy is randomly performed in each half).In treatment protocol in the first visit, the quadrants are equally divided into right and left sides. On one side, only SRP is performed as a control group.After supra and subgingival scaling and whole mouth brossage, In the periodontal pockets of the control side, we put a neutral solution on the gingiva as a placebo and then wash it.The device is placed on the teeth for 60 seconds in a off mode like in the intervention group.The second visit is 1 week later and all previous treatments are repeated.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry

Full name of responsible person

Shabnam Ganjehzadeh

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The beginning of Vakil Abad Blvd, Central Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Rasoul Sahebalam

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Shabnam Ganjehzadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farzaneh Ahrari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Afsaneh Kouhi

Position

Student

Latest degree

Medical doctor

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

Yes - There is a plan to make this available

Title and more details about the data/document

All data will not be published and only data related to the main outcomes included plaque index, bleeding on probing, clinical probing depth and clinical attachment level will be shared.

When the data will become available and for how long

It is possible to access the data from one month after printing the results.

To whom data/document is available

Reputable scientific journals and academic institutions are allowed to request access to the data

Under which criteria data/document could be used

The crude data is provided to people who apply only for statistical analysis.

From where data/document is obtainable

To receive data, the corresponding author should be consulted.

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

After sending the email to the corresponding author, the correctness of applicants information will be checked and after confirmation, the data will be provided.

Comments