Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Afsaneh Kouhi

Name of organization / entity

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Iran (Islamic Republic of)

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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
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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
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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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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