Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of scaling and root surface correction with and without laser on gingival crevicular fluid cytokine levels in patients with chronic periodontitis: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of scaling and root surface correction with and without laser on gingival crevicular fluid cytokine levels in patients with chronic periodontitis

Design

This is a double-blind randomized clinical trial, in which 15 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with chronic periodontitis referring to the School of Dentistry in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 65 years, Chronic periodontitis, Packet depth of 4 to 7 mm without destruction of angular bone, Exclusion criteria: Pregnancy or breastfeeding, Generalized moderate to severe chronic periodontitis, Chronic liver or renal diseases or diabetes, Using tobacco

Intervention groups

Intervention group: On one side of the patient, scaling and root surface correction by a piezoelectric scaling machine with a sharp pen plus laser Cr;YSGG Er with a head of RFTP5 with 1.5 W and 30 hz with angle less than 15 degree parallel to the tooth axis for 10 minutes
Control group: On the other side of the patient, scaling and root surface correction by a piezoelectric scaling machine with a sharp pen

Main outcome variables

Primary outcome: Gingival crevicular fluid cytokine IL-1B levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N379**
Registration date: **2021-02-01, 1399/11/13**
Registration timing: **prospective**

Last update: **2021-02-01, 1399/11/13**
Update count: **0**

Registration date

2021-02-01, 1399/11/13

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-13, 1399/11/25

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of scaling and root surface correction with and without laser on gingival crevicular fluid cytokine levels in patients with chronic periodontitis: a double-blind randomized clinical trial

Public title
Effect of scaling and root surface correction with and without laser on gingival crevicular fluid cytokine levels in patients with chronic periodontitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 20 to 65 years, Chronic periodontitis, Packet depth of 4 to 7 mm without destruction of angular bone,
Exclusion criteria:
Pregnancy or breastfeeding, Generalized moderate to severe chronic periodontitis, Chronic liver or renal diseases or diabetes, Using tobacco

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the right and left sides of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "right" on one sheet and "left" on another. Then, by referring to every patient, one of the sheets will be randomly taken. According to whether the sheet is taken right or left is assigned to the intervention group and the other side to the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The use of the laser as the main intervention on one side of the patient's mouth and not using it on the opposite side will be done simultaneously thus the patient will not be aware which part of the mouth will be affected by the laser. The physician who will examine the patients will not be aware of the intervention. .Thus, the trial will be run as double-blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695

Approval date
2020-12-19, 1399/09/29

Ethics committee reference number
IR.UMSHA.REC.1399.790

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
Gingival crevicular fluid cytokine IL-1B levels

Timepoint
Before the intervention and 3 months later

Method of measurement
Using Elisa test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: On one side of the patient, scaling and root surface correction by a piezoelectric scaling machine with a sharp pen plus laser Cr;YSGG Er with a head of RFTP5 with 1.5 W and 30 hz with angle less than

15 degree parallel to the tooth axis for 10 minutes

Category

Treatment - Other

2

Description

Control group: On the other side of the patient, scaling and root surface correction by a piezoelectric scaling machine with a sharp pen

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry in Hamadan city

Full name of responsible person

Sahar Hemmatian

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School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan 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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Sahar Hemmatian

Position

Resident of Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact
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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