

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the clinical outcomes of conventional periodontal flap surgery versus laser-assisted periodontal flap surgery in patients with moderate to severe chronic periodontitis: a randomized clinical trial

Protocol summary

Summary

Objectives: To compare the clinical outcomes of conventional periodontal flap surgery versus laser-assisted periodontal flap surgery in patients with moderate to severe chronic periodontitis. **Design:** A randomized clinical trial. **Setting and conduct:** The eligible patients with moderate to severe chronic periodontitis who will refer to School of Dentistry during the study period will be enrolled into the trial. **Inclusion criteria:** Age of 18 to 65 years; moderate to severe chronic periodontitis. **Exclusion criteria:** Pregnancy or breastfeeding; chronic disease; using tobacco; a history of gum surgery; angular bone lesions. **Intervention group:** Treatment of periodontitis of one side of the mouth via open flap and removing the granulation tissue by laser with a wavelength of 2780 nm. **Control group:** Treatment of periodontitis of the other side of the mouth via open flap and removing the granulation tissue by conventional surgery. **Primary outcome:** (a) average changes in pocket depth 1 and 3 months after treatment with a clinical examination; (b) average changes in CAL 1 and 3 months after treatment with a clinical examination; (c) average changes of gum resorption 1 and 3 months after treatment with a clinical examination; (d) average changes in the percentage of plaque index 1 and 3 months after the clinical examination; (e) the average changes in the percentage of gum bleeding 1 and 3 months after the treatment with a clinical examination. **Randomization:** Random assignment of the right and left side of the mouth to the intervention and control groups through drawing of lots. **Blinding:** Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201711129014N199**

Registration date: **2017-11-20, 1396/08/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Phone

+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-11-11, 1396/08/20

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the clinical outcomes of conventional periodontal flap surgery versus laser-assisted periodontal flap surgery in patients with moderate to severe chronic periodontitis: a randomized clinical trial

Public title

Comparison of the clinical outcomes of conventional periodontal flap surgery versus laser-assisted periodontal flap surgery in patients with moderate to severe chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 65 years; moderate to severe chronic periodontitis Exclusion criteria: Pregnancy or breastfeeding; chronic disease; using tobacco; a history of gum surgery; angular bone lesions.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the right and left side of the mouth to the intervention and control groups through drawing of lots. Blinding: Not possible.

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

Postal code

Approval date

2017-11-04, 1396/08/13

Ethics committee reference number

IR.UMSHA.REC.1396.525

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

Average changes in pocket depth

Timepoint

1 and 3 months after treatment

Method of measurement

With a clinical examination

2

Description

Average changes in changes in CAL

Timepoint

1 and 3 months after treatment

Method of measurement

With a clinical examination

3

Description

Average changes in gum resorption

Timepoint

1 and 3 months after treatment

Method of measurement

With a clinical examination

4

Description

Average changes in the percentage of plaque index

Timepoint

1 and 3 months after treatment

Method of measurement

With a clinical examination

5

Description

Average changes in the percentage of gum bleeding

Timepoint

1 and 3 months after treatment

Method of measurement

With a clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment of periodontitis of one side of the mouth via open flap and removing the granulation tissue by laser with a wavelength of 2780 nm.

Category

Treatment - Other

2

Description

Control group: Treatment of periodontitis of the other side of the mouth via open flap and removing the granulation tissue by conventional surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Dr Iman Barati

Street address

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

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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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

Vice-chancellor for Research and Technology, Hamadan

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

School of Dentistry

Full name of responsible person

Dr Iman Barati

Position

Resident of Periodontics

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

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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