Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the root coverage with sub-epithelial connective tissue graft with and without root conditioning with laser in patients with gingival recession defect: a randomized clinical trial

Protocol summary

Summary

Objectives: To compare the root coverage with sub-epithelial connective tissue graft with and without root conditioning with laser in patients with gingival recession defect. Design: A randomized clinical trial. Setting and conduct: The eligible patients with gingival recession defect 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; good oral hygiene (plaque index less than 30%); presence of at least 3 mm keratinized gingiva; class I and II gingival erosion defect based on Miller classification; immobility, lack of trauma due to occlusion. Exclusion criteria: Coagulopathy disorders; using alcohol, tobacco, and opioid. Intervention group: Routine treatment plus laser beam once at a distance of 1 to 2 mm from the surface of the root with a wavelength of 2780 nm, the power of 0.75 W, pulse duration of 140 µs, repetition rate of 20 Hz, using 90% water and 40% air through the tip MZ6 model with diameter of 600 mm and length of 6 mm. Control group: Just routine treatment. Primary outcome: Assessing percent coverage of gingival recession 2 weeks and 1 month after treatment with clinical examination. Randomization: Random assignment of teeth on the right and left side of patients to the intervention and control through drawing of lots. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705309014N167**
Registration date: **2017-06-01, 1396/03/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-01, 1396/03/11

Registrant information

Name

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Name of organization / entity

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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

2017-05-22, 1396/03/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the root coverage with sub-epithelial connective tissue graft with and without root conditioning with laser in patients with gingival recession defect: a randomized clinical trial

Public title

Using connective tissue graft for root coverage using root conditioning with laser in comparison with root conditioning without laser

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 65 years; good oral hygiene (plaque index less than 30%); presence of at least 3 mm keratinized gingiva; class I and II gingival recession defect based on Miller classification; immobility, lack of trauma due to occlusion. Exclusion criteria: Coagulopathy disorders; using alcohol, tobacco, and opioid.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

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 teeth on the right and left side of patients to the intervention and control 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 the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2017-05-13, 1396/02/23

Ethics committee reference number

IR.UMSHA.REC.1396.115

Health conditions studied

1

Description of health condition studied

Gingival recession defect

ICD-10 code

K06.0

ICD-10 code description

Gingival recession

Primary outcomes

1

Description

percent coverage of gingival recession

Timepoint

2 weeks and 1 month after treatment

Method of measurement

with clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus laser beam once at a distance of 1 to 2 mm from the surface of the root with a wavelength of 2780 nm, the power of 0.75 W, pulse duration of 140 µs, repetition rate of 20 Hz, using 90% water and 40% air through the tip MZ6 model with diameter of 600 mm and length of 6 mm.

Category

Treatment - Other

2

Description

Control group: Just routine treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Dr Amirarsalan Hooshyarfard

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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
Street address
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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

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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