

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The Effect of Low-Level Laser Therapy on Patient's Pain and Healing of Palatal Donor Site Following Free Gingival Graft

Protocol summary

Summary

The main aim of this study is to evaluate the effectiveness of low level laser therapy on pain and healing of palatal donor site following free gingival graft. This is a randomized controlled clinical trial with split mouth design. Sample size is 12 and selection will be done among patients who need free gingival graft surgery in periodontology faculty of Tehran university of medical sciences. Inclusion criteria are healthy patient with no systemic disease and plaque index $\geq 10\%$ with bilateral lack of keratinized tissue. All surgeries are performed by one surgeon with 1 month interval. After suturing laser irradiation done by operator (immediately after surgery and 1,2,4,7 days after it). laser parameter are Diode, 660 nanometer, power: 200 mW, Continuous wave, time of irradiation: 32 seconds. Patient visits are: 1, 2, 4, 7, 14, 21, 30 and 45 days after surgery and patient pain (VAS), bleeding (question from patient) and epithelialization (by photography) are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206121150N5**

Registration date: **2012-11-30, 1391/09/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-30, 1391/09/10

Registrant information

Name

Neda Moslemi

Name of organization / entity

Tehran university of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Laser research center, Tehran university of medical sciences

Expected recruitment start date

2012-11-10, 1391/08/20

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Low-Level Laser Therapy on Patient's Pain and Healing of Palatal Donor Site Following Free Gingival Graft

Public title

Effect of laser in free gingival graft

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: healthy patient with no systemic disease; plaque index $\geq 10\%$; lack of keratinized tissue around teeth (bilateral). Exclusion criteria: smoking; non-cooperative patients.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 12

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Dentistry, Tehran University of Medical Sciences

Street address

Faculty of Dentistry, Tehran University of Medical Science, Karegar Shomali St, Hakim Hwy

City

Tehran

Postal code

5599114399

Approval date

2012-01-30, 1390/11/10

Ethics committee reference number

91019716886

Health conditions studied

1

Description of health condition studied

free gingival graft

ICD-10 code

K06.0

ICD-10 code description

Gingival recession (generalized) (localized) (postinfective) (post-operative)

Primary outcomes

1

Description

healing of donor site

Timepoint

1,2,4,7,14,21,30,45 days after surgery

Method of measurement

photography

2

Description

epithelialization of donor site

Timepoint

8,14,21 days after surgery

Method of measurement

h2o2 3%

3

Description

pain

Timepoint

1,2,3,4,5,6,7,8 hours and 1,2,3,4,5,6,7,8,14 days after surgery

Method of measurement

VAS and number of tablet

Secondary outcomes

1

Description

bleeding

Timepoint

immediately and 1 day after surgery

Method of measurement

questionnaire

Intervention groups

1

Description

laser irradiatin Diode, 660 nanometer, power:200 mW, Continuous wave, time of irradiation:32 seconds

Category

Other

2

Description

turned off laser

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontology Center, Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Neda Moslemi

Street address

Faculty of Dentistry, Tehran University of Medical

Science, Karegar Shomali St, Hakim Hwy
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Laser Research Center, Tehran University of Medical Sciences

Full name of responsible person

Nasim Chiniforush

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Faculty of Dentistry, Tehran University of Medical Sciences, Karegar Shomali St, Hakim Hwy

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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

Laser Research Center, Tehran 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

Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Mohadeseh Heidari

Position

student of Periodontology

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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