

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of Ga Al As 940nm low-level laser therapy on the healing of human palatal mucosa after free gingival graft surgery:a clinical trial study

Protocol summary

Summary

All patients will receive oral hygiene instructions and initial periodontal therapy to establish optimal plaque control and gingival health. Impression is taken from palatal region to prepare a surgical stent to protect the donor area. Surgical procedures will be carried out by one of the authors not aware of the study groups, according to Sullivan and Atkins technique. A 9*14 mm template made of aluminium foil is used to harvest the standardized graft. A rectangular shape incision with thickness of 1-1.5 mm is prepared in the area between distal finish line of the maxillary canine and distal of the first molar tooth in both groups. Subsequent to graft harvesting, the study group will receive laser irradiation of 940nm GaAlAs 5 J/cm² immediately after surgery and every other day within the following ten days. Postoperative instructions will be provided to each individual. Epithelialization, Remaining Wound Area(RWA) & color match will be evaluated on the day of surgery and on the 7th, 14th, 28th, 60th days after surgery. Pain and secondary bleeding will be measured in the first ten days after surgery through the questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092036203N2**

Registration date: **2017-11-01, 1396/08/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Hoori Asl Roosta

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

no external funding

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Ga Al As 940nm low-level laser therapy on the healing of human palatal mucosa after free gingival graft surgery:a clinical trial study

Public title

The effect of laser therapy on the healing of human palatal wound after free gingival graft surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patents aged between 20 and 70 years old, systemically healthy, keratinized tissue width<1mm, Full Mouth Plaque Score (FMPS)<20%, Full Mouth Bleeding Score (FMBS)<20%, absence of pathological or

morphological alterations in the palatal region (donor site). Exclusion criteria: presence of gag reflex, smoking, presence of proximal bone loss, loss of sensation in palatal mucosa, tooth mobility and/or occlusal trauma in corresponding area, excessive forces (e.g., mechanical forces from orthodontics and traumatic occlusions), systematic diseases that would contraindicate periodontal surgery or interfere with tissue healing such as diabetes, chronic high dose steroid therapy, history of radiation or immuno-suppressive therapy, pregnancy, lactation, gastro-intestinal problems, hyper sensitivity to impression materials, history of drug therapies that are known to interfere with healing or cause gingival enlargement, and patients not complying with postoperative protocols and/or attending their visits irregularly.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Dentistry Faculty of Tehran
University of Medical Sciences

Street address

Dentistry Faculty of Tehran University of Medical
Sciences, North Karegar St, Tehran, Iran

City

Tehran

Postal code**Approval date**

2017-09-10, 1396/06/19

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1396.3394

Health conditions studied**1****Description of health condition studied**

Palatal wound after free gingival graft surgery

ICD-10 code

K13.7

ICD-10 code description

Other and unspecified lesions of oral mucosa

Primary outcomes**1****Description**

Remaining Wound Area

Timepoint

On the day of surgery and on the 7th , 14th, 28th, 60th
days after surgery

Method of measurement

Image J software (mm2)

Secondary outcomes**1****Description**

Pain

Timepoint

The first 10 days after surgery

Method of measurement

Questionnaire (VAS)

2**Description**

Epithelialization

Timepoint

On the 7th , 14th, 28th, 60th days after surgery

Method of measurement

By means of bubble formation after dripping hydrogen
peroxide (3%) to the wound surface (total, partial or
none)

3**Description**

Secondary bleeding

Timepoint

The first 10 days after surgery

Method of measurement

Questionnaire

4**Description**

Colour Match (brightness parameters)

Timepoint

On the 7th , 14th, 28th, 60th days after surgery

Method of measurement

Adobe photoshop software

Intervention groups

1

Description

The patients allocated for the test group will receive the following protocol for laser application: A GaAlAs laser will be used for irradiation at a wavelength of 940 nm, an intensity that had been previously calibrated by the manufacturer.(Ezlase; Biolase Technology Inc., Irvine,CA, USA). The wounds of each experimental group receive laser stimulation at doses of 5J/cm². The power output is maintained at a constant 0.21 W in the continuous-wave (cw) mode; The spot size is 1.26 cm², the total energy dose per session is 6.3 J, and powerdensity is 0.16 W/cm². Laser energy will be applied via a 400 micron optical fiber. The optical fiber is positioned at a distance of approximately 5 mm proximal to the wound, and the irradiation time is 30 s. The experimental groups will receive their first dose of irradiation immediately after surgery and within ten days, one day apart following the surgery for a total of 5 sessions.

Category

Rehabilitation

2

Description

The patients allocated to the control group will receive sham irradiation. For this, rubber protection is placed at the tip of the laser device, which don't allow the light to reach the tissue. The applications will be performed by a different operator from the one who measure the study parameters.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry Faculty of Tehran University of Medical Sciences

Full name of responsible person

Ghazal Morshedzade Tehrani

Street address

Department of Periodontology, Thired floor, Dentistry Faculty of Tehran University of Medical Sciences, North Karegar St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private

Full name of responsible person

Ghazal Morshedzade Tehrani

Street address

Dentistry Faculty of Tehran University of Medical Sciences, North Karegar St, Tehran

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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

Private

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

Dentistry Faculty of Tehran University of Medical Sciences

Full name of responsible person

Ghazal Morshedzade Tehrani

Position

dentistry student

Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Dentistry Faculty of Tehran University of Medical
Sciences

Full name of responsible person

Ghazal Morshedzade Tehrani

Position

Dentistry student

Other areas of specialty/work

Street address