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 mocusa 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

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Name of organization / entity

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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 mocusa 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
Questionaire (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
Questionaire

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Private

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
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
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dentistry student

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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