

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Dimensional changes in free gingival grafts: scalpel versus Er:YAG laser-- an rct study

Protocol summary

Study aim

Dimensional changes in free gingival grafts: scalpel versus Er:YAG laser

Design

RCT-split mouth -double blinded

Settings and conduct

Tehran university of medical sciences faculty of dentistry

Participants/Inclusion and exclusion criteria

Age older than 18 years requires increased attached gingiva width in the mandibular premolar area(Keratinized gingiva less than 2mm or attached gingiva less than 1mm) Patients' health in terms of systemic and periodontal conditions (probe depth less than 3 mm or BOP Grade 1 or less) good plaque control (plaque index less than 20%) Ability to adapt the patient to the study-related processes 1- heavy smoker (those who smokes more than 10 cigarettes a day) Having a systemic problem that has a negative effect on wound healing. And taking medications that interfere with surgical repair pregnant patients Use of antibiotics over the past 6 months

Intervention groups

Intervention group: In these patients, the receptor bed of graft is prepared by Er: cr: YSGG laser (manufactured by the United States Biolase company with 2 watts, 50Hz, 60% water and 30% air). In the second stage, which is similar between the two groups, the free gingival graft is harvested from the palatal area and then sutured with nylon 0-4 thread Control group: In these patients, the receptor bed of the graft is prepared by the common method, which is the blade (No. 15). In the second stage, which is similar between the two groups, free gingival graft is harvested from the palatal area and is sutured with nylon 0-4 thread

Main outcome variables

Graft size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170916036203N3**

Registration date: **2018-05-04, 1397/02/14**

Registration timing: **retrospective**

Last update: **2018-05-04, 1397/02/14**

Update count: **0**

Registration date

2018-05-04, 1397/02/14

Registrant information

Name

Hoori Asl Roosta

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8849 2345

Email address

h-aslroosta@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Dimensional changes in free gingival grafts: scalpel versus Er:YAG laser--an rct study

Public title

dimensional change in gingival graft ,scalpel versus graft

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age older than 18 years requires increased attached gingiva width in the mandibular premolar area(Keratinized gingiva less than 2mm or attached gingiva less than 1mm) Patients' health in terms of systemic and periodontal conditions (probe depth less than 3 mm or BOP Grade 1 or less) good plaque control (plaque index less than 20%) Ability to adapt the patient to the study-related processes

Exclusion criteria:

1- heavy smoker (those who smokes more than 10 cigarettes a day) Having a systemic problem that has a negative effect on wound healing. And taking medications that interfere with surgical repair pregnant patients Use of antibiotics over the past 6 months

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

The sample consists of 10 patients as test and control(split mouth)

Randomization (investigator's opinion)

Randomized

Randomization description

simple individual randomization by sealed envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participant, and data collectors are blind to the study. on the day of surgery the patients will receive the laser light on both side ,but on control side without energy and on the test site the patients will receive energy.on the follow up visits a person that is blind to the study will record the data

Placebo

Not 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

Province

Tehran

Postal code

1439955991

Approval date

2017-10-02, 1396/07/10

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1396.3594

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

Dimensional changes in gingival graft after 6 months

ICD-10 code

K06.9

ICD-10 code description

Disorder of gingiva and edentulous alveolar ridge, unspecified

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

Dimensional changes of free gingival grafts in two substrates prepared with Orbium Laser Er: Cr: YSGG and the Scalpel Common Method

Timepoint

1st, 3rd and 6th months after surgery

Method of measurement

Image J software (mm2)

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

Duration of surgery

Timepoint

Surgical day

Method of measurement

Time in minutes

2

Description

pain

Timepoint

The first 10 days after surgery

Method of measurement

Questionnaire (VAS)

3

Description

Swelling

Timepoint

The first 10 days after surgery

Method of measurement

questionnaire and patient examination

4

Description

hematoma

Timepoint

the first 10 days after surgery

Method of measurement

questionnaire

5

Description

Colour Match (brightness parameters)

Timepoint

6 month after surgery

Method of measurement

adobe photoshop

Intervention groups

1

Description

Intervention group: In these patients, the receptor bed of graft is prepared by Er: cr: YSGG laser (manufactured by the United States Biolase company with 2 watts, 50Hz, 60% water and 30% air). In the second stage, which is similar between the two groups, the free gingival graft is harvested from the palatal area and then sutured with nylon 0-4 thread

Category

Treatment - Surgery

2

Description

Control group: In these patients, the receptor bed of the graft is prepared by the common method, which is the blade (No. 15). In the second stage, which is similar between the two groups, free gingival graft is harvested from the palatal area and is sutured with nylon 0-4 thread

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry Faculty of Tehran University of Medical Sciences

Full name of responsible person

Hamed rahimi

Street address

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

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8821 3507

Email

hamedr2003@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Marzieh Alikhasi

Street address

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

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8821 3507

Email

malikhasi@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hamed Rahimi

Position

post graduate student of periodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Department of Periodontology, Third floor, Dentistry

Faculty of Tehran University of Medical Sciences,

North Karegar St, Tehran

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8821 3507

Email

hamedr2003@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Afshin Khorsand

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

Street address

Department of Periodontology, Third floor, Dentistry

Faculty of Tehran University of Medical Sciences,

North Karegar St, Tehran

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8821 3507

Email

a_afshin_khorsand@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hamed Rahimi

Position

Post graduate student of periodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Department of Periodontology, Third floor, Dentistry

Faculty of Tehran University of Medical Sciences,

North Karegar St, Tehran

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8821 3507

Email

hamedr2003@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participants' data will be shared after they are unidentified.

When the data will become available and for how long

Access to data will be available after the publication of the article.

To whom data/document is available

Data will be available to researchers inside and outside the university

Under which criteria data/document could be used

All data and analyzes are available on referral terms

From where data/document is obtainable

To access, please contact Hamed Rahimi at the email address hamedr2003@yahoo.com.

What processes are involved for a request to access data/document

After sending a request by email, within a week, data will

be shared

Comments