Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 bye 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
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Hoori Asl Roosta
Name of organization / entity
Tehran University of Medical Sciences
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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 envelops
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 fallow 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
Questionaire (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
questionaire

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 bye 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Marzieh Alikhasi
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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 periodantics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Afshin Khorsand

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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