Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

Comparison morbidity in donor site and color matching in recipient site between two different free connective tissue graft harvesting technique from palate

Protocol summary

Study aim

Comparison complications after surgery and color matching of free connective tissue graft between two different methods of harvesting graft from the palate

Design

This study is a clinical trial with a control group, with parallel groups, a blind strain, split mouth and randomized. Sealed envelopes have been used for randomization.

Settings and conduct

The patient and the evaluators in the 6-month follow-up are blind. Only the researcher is aware of the used methods

Participants/Inclusion and exclusion criteria

1- Bilateral areas in the jaw where the teeth have gingival recession 2- The bilateral areas affected by the recession should have approximately the same recession depth 3- There should be no interdental soft tissue CAL in the areas with recession (Miller 1 and 2) 4- The thickness of the palate in people should be at least 2 mm 5- Absence of signs of inflammation in the teeth located in the area of gingival recession 6- The presence of a sulcus with a depth of < 3 mm 7- People must be over 18 years of age 8- There is no history of harvesting the graft from palate Smokers who smoke more than 10 cigarettes per day, pregnant women, people who take drugs that affect periodontal tissues and healing and teeth in the surgical area with mobility or improper root treatment were excluded from the study.

Intervention groups

The surgical technique in the control group is the trap door method and in the test group, the method is harvesting epithelialized graft and then de-epithelialization outside the mouth.

Main outcome variables

1- Comparison of the amount of pain in the donor sites 2- The comparison of the amount of shrinkage in the recipient sites 3- Comparison of color matching in the resulting tissue at the recipient site 4- Comparison of the thickness of the resulting tissue in the recipient site 5- Comparison of coverage obtained for gingival recession

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230102057017N1**
Registration date: **2023-01-30, 1401/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-30, 1401/11/10**
Update count: **0**

Registration date

2023-01-30, 1401/11/10

Registrant information

Name

Amine Beymouri

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-16, 1401/10/26

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison morbidity in donor site and color matching in recipient site between two different free connective tissue graft harvesting technique from palate

Public title

Comparison of 2 methods of gingival connective tissue grafting in terms of patient comfort and grafted tissue quality

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Bilateral areas in the jaw where the teeth have gingival recession. If the number of teeth affected by recession on both sides of the jaw is not the same, the area with a smaller size is the criterion, and the same number of teeth is considered on the opposite side of the surgical site The bilateral areas affected by the analysis should have approximately the same recession depth There should not be CAL interdental soft tissue in the areas with recession (Miller 1 and 2) The presence of a sulcus with a depth < 3 mm The thickness of the palate in people should be at least 2 mm Absence of signs of inflammation in the teeth located in the area of gum augmentation (such as BOP, enlargement, pus) or if there is, performing periodontal treatment and controlling the symptoms People over 18 years old There is no history of graft harvesting from palate

Exclusion criteria:

Smokers who smoke more than 10 cigarettes per day Pregnant women People who take drugs that affect periodontal tissues and healing of tissues Teeth in the surgical area with mobility or improper root treatment

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **12**

More than 1 sample in each individual

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

Connective tissue graft surgery

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the donor and recipient areas are both on the same side. To determine the direction and type of surgery, trap door-left, trap door-right, deepithelization-right and deepithelization-left are written in 4 envelopes. On the day of the surgery and just before the surgery, one of the envelopes is removed to determine the direction and type of surgery for the first session. About 4 to 2 weeks later (depending on the extent of recovery and improvement of the patient's pain symptoms), another surgical procedure will be performed on the opposite side.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient and the evaluators in the 6-month follow-up are unaware of the surgical method used in each side. Only the researcher who performs the surgeries herself is aware of the method used in each direction.

Placebo

Not used

Assignment

Parallel

Other design features

This study will be conducted as a split mouth randomized controlled clinical trial. The surgical technique in the control group was the trap door method and in the test group, the preparation method was epithelialization and then de-epithelialization outside the mouth.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical sciences

Street address

North Karegar Street, Dentistry Faculty of Tehran University Medical Sciences

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2021-08-01, 1400/05/10

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1400.197

Health conditions studied

1

Description of health condition studied

Gingival recession

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Evaluation the pain level of the patient in the donor area which is measured based on the Visual Analogue Scale
Timepoint
The third and seventh day after surgery
Method of measurement
Visual Analogue Score

Secondary outcomes

1

Description
Graft shrinkage in recipient site
Timepoint
6 months after surgery
Method of measurement
The ratio of the grafted area in recipient site to the initial area of the graft before suturing, which is measured by Image J software

2

Description
Evaluating the degree of color matching in the recipient area
Timepoint
6 months after surgery
Method of measurement
The score of 3 blind professor regarding the method used and averaging them

3

Description
Evaluating the thickness of grafted site
Timepoint
6 months after surgery
Method of measurement
Ultrasonography

Intervention groups

1

Description
Intervention group: The group in which graft harvested from the palate in an epithelialized form
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
Amine Beymouri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Amine Beymouri

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available