Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the success rate of free gingival graft treatment with and without using periodontal dressing in increasing keratinized gingival width and vestibule depth: a randomized clinical trial

Protocol summary

Study aim
Determination of the success rate of free gingival graft treatment in increasing keratinized gingival width and vestibule depth with and without using periodontal dressing

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 26 patients. Randomization is done in a simple and individual way, and a table of random numbers is used for randomization.

Settings and conduct
The study is in the field of improving the quality of gingival tissue. Gingival transplant surgery will be performed for patients without sufficient keratinized gingiva in two groups, with and without using periodontal dressings, at Tehran Faculty of Dentistry. The researcher and the analyst are blinded to the study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: people who have placed at least two implants at the posterior of the mandible due to partial edentulousness (as the most posterior teeth); Patient who have insufficient vestibular depth in this place. Exclusion criteria: systemic disease that interferes with wound healing; alcohol and drug abuse; smoking; uncontrolled periodontal disease; pregnant and lactating mothers; patients with parafunctional habits.

Intervention groups
Intervention group: Free gingival graft surgery is performed in the edentulous area posterior of the mandible. The graft is harvested from the palate area. Finally, it is fixed in the intended place with stitches. Then, in patients, periodontal dressing is used in the place of fixation. Control group: Free gingival graft surgery is performed in the edentulous area posterior of the mandible. The graft is harvested from the palate and fixed in the desired place with sutures.

Main outcome variables
The depth of the vestibule; Keratinized gingiva.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231115060072N1**
Registration date: **2023-12-12, 1402/09/21**
Registration timing: **prospective**

Last update: **2025-03-30, 1404/01/10**
Update count: **1**

Registration date
2023-12-12, 1402/09/21

Registrant information

Name
Amirmohammad Dolatabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4279 4000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-08, 1403/01/20

Expected recruitment end date
2024-10-11, 1403/07/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the success rate of free gingival graft treatment with and without using periodontal dressing in increasing keratinized gingival width and vestibule depth: a randomized clinical trial

Public title

The success rate of gum grafting with and without dressing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People who have placed at least two implants at the posterior of mandible due to partial edentulousness (as the most posterior teeth). Patients who have insufficient vestibular depth at the implants placement site.

Exclusion criteria:

Systemic disease that interferes with wound healing. Alcohol and drug abuse Cigarette smoking Uncontrolled periodontal disease Pregnant and lactating mothers Patients with parafunctional habits

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple and individual randomization; People who meet the entry criteria are assigned a number and enter the study. Then, each number representing the patient is placed in one of the 2 intervention and control groups by the random number table. Sealed envelope method will be used for allocation concealment. Determining the placement of the dressing is written in the envelope for each patient, then on the day of the surgery, and at the end of that, the envelope for the patient is opened, and based on that, the dressing is placed or not at the surgery site.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and the statistical analyst are blinded to the type of surgical technique performed in each patient. The data in two groups A and B will be given to the analyzer without mentioning whether each group is a test or a control. There is no possibility of blinding the patients due to the observation of the dressing in the mouth. Also, until the end of the surgery and the placement of the dressing, the surgeon is unaware of which group the patient is in, so that the surgical procedure does not differ between the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

No. 31, Safavyan Alley, Sattar Khan Street, Tehran

City

Tehran

Province

Tehran

Postal code

1444783911

Approval date

2023-11-15, 1402/08/24

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1402.081

Health conditions studied

1

Description of health condition studied

Gingival transplant surgery technique

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Vestibular depth

Timepoint

At the beginning of the study, 1 month after surgery, 3 months after surgery

Method of measurement

Intraoral scanner

2

Description

Keratinized gingiva

Timepoint

At the beginning of the study, 1 month after surgery, 3 months after surgery

Method of measurement

Periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Free gingival graft surgery is performed in the edentulous area posterior of the mandible. The graft is harvested from the palate. Finally, it is fixed in the intended place with stitches. Then, in patients, periodontal dressing is used in the fixation place.

Category

Treatment - Surgery

2

Description

Control group: Free gingival graft surgery is performed in the edentulous area posterior of the mandible. After preparing the recipient bed, the graft is harvested from the palate. Finally, the grafted tissue is fixed in the intended place with sutures.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Neda Moslemi

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Sponsors / Funding sources

1

Sponsor

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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

Amirmohammad Dolatabadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Medical doctor

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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