

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect on the width of keratinized gingiva Mucograft prototype in comparison with the free gingival graft

Protocol summary

Summary

This prospective split-mouth will be compared the use of a collagen matrix (mucograft) to an autogenous gingival graft (FGG) in the ability to increase the zone of keratinized attached gingiva. 12 patients with inadequate amounts of keratinized attached gingiva bilaterally in the posterior mandible will be enrolled using a split-mouth design. The maintenance of periodontal health and the patient morbidity will be assessed pre-operatively at 1, 3 and 6 months. Clinical variables including plaque index (PI), gingival index (GI), probing depth (PD), attached tissue width (AT), and clinical attachment level (CAL) will be recorded immediately before surgery and at 1, 3 and 6 months postoperative visit. Patients will be seen at 2, 4, 6, 8, and 12 weeks to monitor wound healing and oral hygiene performance (PI and GI). Graft width will be also measured, in coronal-apical direction, on individually involved teeth during the surgery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052813501N1**

Registration date: **2014-12-16, 1393/09/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-16, 1393/09/25

Registrant information

Name

Hadi Zare

Name of organization / entity

Faculty Of Dentistry, Tehran University of Medical

Sciences

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Recruitment status

Recruitment complete

Funding source

School of Dentistry, Tehran University of Medical Sciences and Research Funding

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect on the width of keratinized gingiva Mucograft prototype in comparison with the free gingival graft

Public title

The effect of gingival graft by mucograft and autologous tissue graft that harvested from palate in the gingival tissue created in the same person

Purpose

Treatment

Inclusion/Exclusion criteria

Patient inclusion criteria were ; the patients older than 18 years and systemic and periodontal patients healthy ; patients with at least 2 region (Split Mouth) gingival grafts are needed. Exclusion criteria for patients from the study; Patients with systemic problems (diabetes, Immunocompromised patients, patients with chronic

diseases such as hepatitis, etc.) ; Patients who consume more than 10 cigarettes per day ; patients with plaque index more than 15% ; patients who are allergic to collagen are determined

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

This study will be held as a split mouth study which both surgical methods will be introduced simultaneously on one patient.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Enghelab square

City

Tehran

Postal code

Approval date

2012-06-30, 1391/04/10

Ethics committee reference number

91-04-10-18791-78324

Health conditions studied

1

Description of health condition studied

gingival recession and inadequate amounts of keratinized attached gingiva

ICD-10 code

K06.0

ICD-10 code description

Gingival recession

Primary outcomes

1

Description

keratinized tissue width

Timepoint

pre-operatively and 1, 3 and 6 months later intervention

Method of measurement

will be measured by UNC-15 probe

2

Description

Pain reduction by new technique

Timepoint

first , 3th , 5th , 7th after intervention

Method of measurement

according to visual analogue scale

Secondary outcomes

1

Description

surgery time reduction by new material

Timepoint

From the beginning to the end of surgery

Method of measurement

According to the minutes of by the stopwatch

Intervention groups

1

Description

The study, which will be split-mouth. Two surgeries will be done in a patient, on the one side Mucograft material and the other side using graft that will be harvested from the palate of the patient. first premolar will be selected as target for gingival transplant surgery by mucograft material or graft that harvested from the palatal. by the Bjorn technique surgery will be done .The size of the graft material in both site will be 10 x 20 mm and used 5 suture for tissue fixation

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

dr Hadi Zare

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Faculty Of Dentistry, Tehran University of Medical Sciences, Research department
Full name of responsible person
dr Amir Reza Rokn,
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Reasearch assistant director
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Tehran

Grant name

Grant code / Reference number

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

Title of funding source

Faculty Of Dentistry, Tehran University of Medical Sciences, Research department

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

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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