

# 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

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##### Country

Iran (Islamic Republic of)

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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

##### **Street address**

Faculty Of Dentistry , North Karegar, Amir Abad  
**City**  
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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,  
**Street address**  
Reasearch assistant director  
**City**  
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

### Contact

**Name of organization / entity**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*