Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of biologic dressing on the wound healing of the palatal donor site in free gingival graft technique

Protocol summary

Summary

objectives: to evaluate the effect of application of the biologic dressing on donor palatal wound healing and pain level. design: 24 consecutive patients who referred to the periodontics department of dental school (TUMS) will be allocated into test and control groups.by closed envelope tech. setting and conduct: in both groups free gingival graft surgeries have been conducted., in test group after graft harvesting, the palatal donor site is covered by biologic dressing and the dressing will be sutured. In the control group, the palatal donor site will be sutured and left uncovered to heal. participants: healthy subject who needs gingival augmentation by free gingival graft technique in any parts of the gingiva will be included. patients with systemic diseases interfered with healing are excluded. main out comes: the following parameters will be assessed in 7,14 and 21 days after surgery. parameters: 1- pain scores by visual analog scale 2- number of medication taken for pain relief in first week after surgery. 3- healing rate of donor site: photographs is taken and healing process will be analysed according to color match, tissue texture and contour.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021321069N1**
Registration date: **2016-06-13, 1395/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-13, 1395/03/24

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tehran University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of biologic dressing on the wound healing of the palatal donor site in free gingival graft technique

Public title

effect of biologic dressing on the palatal wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: healthy subject who needs gingival augmentation by free gingival graft technique in any parts of the gingiva will be included. exclusion criteria: patients with non controlled diabetes;patients with

immune deficiency diseases or who received immunosuppressive medications; smokers; pregnant and /or lactating women

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

randomization by closed envelope technique

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Tehran University of Medical Science

Street address

central building of Tehran University of Medical Science, ghods Ave, keshavarz Blvd

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tehran

Postal code

Approval date

2016-04-11, 1395/01/23

Ethics committee reference number

IR.TUMS.REC.1395.2375

Health conditions studied

1

Description of health condition studied

palatal wound healing following free gingival graft surgeries

ICD-10 code

k06.9

ICD-10 code description

Disorder of gingiva and edentulous alveolar ridge, unspecified

Primary outcomes

1

Description

severity of pain after harvesting graft from palatal area

Timepoint

7,14 and 21 days after surgery

Method of measurement

VAS (Visual Analogue Scale) 0= no pain, 10= the most sever pain had been experienced

Secondary outcomes

1

Description

healing rate of palatal donor area

Timepoint

7,14 and 21 days after syrgery

Method of measurement

evaluation of photographies by 2 investigators

Intervention groups

1

Description

In test group after controlling the bleeding with a wet gauze , the biologic dressing is placed on the donor site ad is sutured to the adjacent area

Category

Treatment - Surgery

2

Description

In control participants: after harvesting the tissue from the palate, gauze is kept in place to stop Bleeding and the wound will be sutured.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

periodontics department of dental school, tehran university of medical science

Full name of responsible person

zeinab kadkhoda

Street address

north karegar Ave,periodontics department of dental school, tehran university of medical science

City

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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
vice chancellor for research, Tehran University of Medical Science
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*