Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of allograft in gingival augmentation compared to free gingival graft in patients with deficient attached gingiva

Protocol summary

Summary

Objective: The purpose of this study is to compare the effect of allograft to free gingival graft in increasing the attached gingiva width. Design: Thirty patients, with attached gingiva ≤1 mm on the facial aspect of teeth demonstrating a tendency of progressive marginal tissue recession, will randomly be assigned to either test or control treatment using the SPSS software. Setting and conduct: fifteen patients will receive allograft/ CenoDerm (test) and 15 patients will receive an free gingival graft (control). Participants: Patients with utmost 1 mm attached gingiva will be included and patients who fail to attend the recall visits will be excluded from the study. Clinical variables including plaque index (PI), gingival index (GI), probing depth (PD), attached tissue width (AT), and gingival recession (GR) will be recorded immediately before surgery and at the 3-month postoperative visit. Patients will be seen at 2 and 12 weeks to monitor wound healing and oral hygiene performance (PI and GI). Main outcome: Graft width will be measured, in corono-apical direction, on individually involved teeth during the surgery and 3 months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051222249N1**
Registration date: **2015-06-13, 1394/03/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-13, 1394/03/23

Registrant information

Name

Kimia Najafi Khotbesara

Name of organization / entity

Qazvin University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

institution

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of allograft in gingival augmentation compared to free gingival graft in patients with deficient attached gingiva

Public title

The effect of synthetic material in gingival reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients referred to Qazvin faculty of dentistry in 2014, who need a gingival augmentation due to gingival diseases, trauma or anatomic variations. All the participants should: 1) Practice adequate oral hygiene procedures regularly. 2) Have at least one teeth with gingival height <= 1 mm in need of gingival

augmentation. 3) Have a probing depth <=3 mm in aforesaid tooth. 4) Not have any systemic diseases. 5) Not be smoker. Exclusion criteria: Failure to attend the recall visits.

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: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Each patient will receive a code and will randomly be assigned to either test or control group using the SPSS software.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences.

Street address
Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

City
Qazvin

Postal code
59811-34197

Approval date
2015-03-16, 1393/12/25

Ethics committee reference number
28/20/10038

Health conditions studied

1

Description of health condition studied
inadequate attached gingiva

ICD-10 code
K06.9

ICD-10 code description
Disorder of gingiva and edentulous alveolar ridge, unspecified

Primary outcomes

1

Description
attached gingiva width

Timepoint
baseline, 14 days post operation, 12 weeks post operation

Method of measurement
periodontal probe

Secondary outcomes

1

Description
inflammation, periodontal pocket

Timepoint
baseline, 12 weeks post operation

Method of measurement
gingival index, probing depth

Intervention groups

1

Description
Control: The Free Gingival Graft (FGG) is a surgical procedure frequently used in periodontics to increase the amount of keratinized tissue surrounding a tooth or a dental implant. The major limitation to the use of the FGG technique is the need for a donor site. Amongst others are anatomic limitations, color and texture mismatch with surrounding tissue that encouraged researchers to find proper alternatives for this technique.

Category
Treatment - Surgery

2

Description
Intervention: ADMs are soft tissue matrix grafts created by a process that results in decellularization but leaves the extracellular matrix intact. This matrix provides a scaffold upon and within which the patient’s own cells can repopulate and revascularize the implanted tissue. Its utility has been demonstrated in various reconstructive techniques, such as gingival augmentation, root coverage, GBR, GTR.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontics department, Qazvin University of Medical Sciences, Qazvin, Iran.

Full name of responsible person

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin university of medical sciences.

Full name of responsible person

Dr. Taghi Naserpour Farivar,

Street address

Vice chancellor for research, Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

City

Qazvin

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, Qazvin university of medical sciences.

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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Kimia Najafi

Position

periodontics resident

Other areas of specialty/work

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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