

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of amnion allograft with free gingival graft to improve the attached mucosa around dental implants

Protocol summary

Summary

28 participants in both control and test groups (14 patients in each group) receive mucogingival surgery to increase the width of attached keratinized peri-implant mucosa. They should have at least one implant lacking attached mucosa on the buccal side. Baseline measurements includes the width of keratinized gingiva in the buccal side of implants (as primary outcome), plaque index, gingival index and probing pocket depth in adjacent natural teeth. Furthermore, surface texture and color are recorded using photographs. For both groups, the recipient bed is prepared using a surgical blade (number 15), beginning from the mucogingival line, as a split thickness periosteal bed. Muscle attachments are incised to create a periosteal bed. The mucosal flap is sutured to the buccal mucosa or it is removed. For the participants in the control group, a free gingival graft is harvested from the palatal area. The graft size is determined using an aluminum foil placed on the recipient bed. The gingival graft is stabilized by 4-0 vicryl absorbable sutures. In the test group, an amniotic membrane graft is cut to the appropriate size, then, it is fixated using the similar sutures. Immediately after homeostasis, the width measurement and clinical measurements are repeated. The measurements are repeated after the 1st, 2nd, 6th and 12th weeks. The participants are asked to fill the VAS pain related questionnaire in every recall sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101621069N2**

Registration date: **2017-03-16, 1395/12/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-16, 1395/12/26

Registrant information

Name

zeinab kadkhoda

Name of organization / entity

Tehran university of medical sciences, faculty of dentistry.

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 5801

Email address

zkadkhoda@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

research center of the Iranian Tissue Bank

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of amnion allograft with free gingival graft to improve the attached mucosa around dental implants

Public title

amnion allograft for increasing the width of peri-implant attached mucosa

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients age more than 18 years; systemic and periodontal health; at least one implant with less than 1 mm attached mucosa after the stage 1 implant insertion surgery; favorable plaque control (less than 20% olery plaque index); patients should be able to afford the related procedures.

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 28

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of the Tehran University of Medical Sciences

Street address

6th floor, central organization of TUMS, keshavarz street, Tehran, Iran

City

Tehran

Postal code

Approval date

2017-02-04, 1395/11/16

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1608

Health conditions studied

1

Description of health condition studied

lack of attached mucosa around dental implants

ICD-10 code

K06.0

ICD-10 code description

Gingival recession

Primary outcomes

1

Description

width of attached peri-implant mucosa

Timepoint

before surgery, immediately after surgery, after the 1st, 2nd, 6th and 12th postoperative weeks

Method of measurement

measurement of the distance between mucosal margin to the mucogingival line in the midbuccal of each implants using UNC-15 periodontal probe - probing depth

Secondary outcomes

1

Description

post-operative pain

Timepoint

after the 1st, the 2nd, the 6th and the 12th postoperative weeks

Method of measurement

visual analogue scale (VAS)

Intervention groups

1

Description

In the control group, participants recieve free gingival graft (from palate) to increase the width of attached mucosa around implants. In the test group, patients are treated with amniotic allogenic membrane for the same purpose.

Category

Treatment - Surgery

2

Description

in test group, the attached peri-implant mucosa is augmented using allogenic amniotic membrane. in the control group, free gingival graft from the palatal mucosa is performed to increase the attached peri-implant mucosa

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

postgraduate section, department of periodontology, school of dentistry, TUMS

Full name of responsible person

Dr Hossein Babazade

Street address

3rd floor, school of dentistry

City

north karegar street

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian Tissue Bank Research Center

Full name of responsible person

Masoud Younesian

Street address

Room no.601, 6th floor, Central Organization TUMS,
Ghods street, Keshavarz street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian Tissue Bank Research Center

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

school of dentistry, TUMS

Full name of responsible person

Dr Babazade

Position

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Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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