

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 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**

post graduate student

**Other areas of specialty/work**

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## Person responsible for scientific

## inquiries

**Contact**

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**Full name of responsible person**

Dr Zeinab Kadkhoda

**Position**

Associate Professor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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school of Dentistry, TUMS

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Dr Hoori Aslroosta

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assistant professor

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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*