

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Clinical comparison of two different approach of De-epithelialization of free gingival graft using surgical blade and diamond bur in thickness and width of peri-implant keratinized tissue

#### Protocol summary

##### Study aim

Comparison of the width and thickness of peri-implant keratinized tissue following the use of de-epithelialized free gingival graft using surgical blade and diamond bur

##### Design

The study was a single-blind splith-mouth clinical trial and the available non-random sampling method was used.

##### Settings and conduct

The study was performed on 20 patients referred to the periodontics department of Islamic Azad University, Isfahan Branch before receiving the final implant prosthesis. The recipient site was prepared by the envelope flap technique. to prepare the d-fgg by bur, the superficial epithelial layer removed by diamond bur and a high-speed handpiece to the depth of about 0.5-1 mm, then the tissue is separated from the palate and to prepared the d-fgg by blade, the graft is separated from the palate in partial thickness, then the superficial epithelial layer is removed using a blade. The connective tissue is guided to recipient site by absorbable monofilament 0-5 suture and sutured to the flap.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: 1.Partial edentulous patient with at least 2 dental implants 2.Insufficient keratinized tissue around implants (width less than 2 mm and / or thickness less than 2 mm) 3.Presence of buccal bone around the implant 4.Good oral hygiene 5.Identical implants in terms of shape and brand in each patient exclusion criteria: 1.uncontrolled systemic disease 2.Smoking more than 10 cigarettes a day 3.History of mental disorder 4.Periodontal disease or local inflammation 5.History of implant failure or tissue grafting 6.Poor oral health 7.Drugs affect on tissue repair 8.History of tissue augmentation in the area

##### Intervention groups

Intervention : de-epithelialization of the fgg using

diamond bur Control : de-epithelialization of the fgg using surgical blade

##### Main outcome variables

width of keratinized tissue thickness of keratinized tissue

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220427054680N1**

Registration date: **2022-06-20, 1401/03/30**

Registration timing: **retrospective**

Last update: **2022-06-20, 1401/03/30**

Update count: **0**

##### Registration date

2022-06-20, 1401/03/30

##### Registrant information

##### Name

nasim maghamipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1535 4053

##### Email address

n.maghamipour@khuif.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-16, 1400/07/24

##### Expected recruitment end date

2021-12-25, 1400/10/04

##### Actual recruitment start date

2021-10-17, 1400/07/25  
**Actual recruitment end date**  
2022-01-23, 1400/11/03  
**Trial completion date**  
empty

**Scientific title**  
Clinical comparison of two different approach of De-epithelialization of free gingival graft using surgical blade and diamond bur in thickness and width of peri-implant keratinized tissue

**Public title**  
Clinical comparison of two different approach of De-epithelialization of free gingival graft using surgical blade and diamond bur

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Partial edentulous patient with at least 2 dental implants ready to receive prosthesis Insufficient keratinized tissue around implants (keratinized gingival width less than 2 mm and / or keratinized gingival thickness less than 2 mm) Presence of buccal bone around the implant Good oral hygiene (FMPS, FMBS <25%) Identical implants in terms of shape and brand in each patient  
**Exclusion criteria:**  
Existence of uncontrolled systemic disease Smoking more than 10 cigarettes a day History of mental disorder Periodontal disease or local inflammation History of implant failure or tissue grafting in the area Poor oral health (25%> FMBS) Consumption of drugs effective in tissue repair History of soft or hard tissue augmentation in the area

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **20**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
Case and control groups as split-mouth in one person  
Actual sample size reached: **20**  
More than 1 sample in each individual  
Actual sample size in each individual: **2**  
Case and control groups as split-mouth in one person

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The person who collected the data and evaluated the outcome was someone other than the surgeon and is

kept blind  
**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**  
split-mouth

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Islamic Azad University - Isfahan Branch (Khorasgan)

##### Street address

Arghavaniyeh street, Eastern Jey Street

##### City

isfahan

##### Province

Isfahan

##### Postal code

8155139998

#### Approval date

2021-11-13, 1400/08/22

#### Ethics committee reference number

IR.IAU.KHUISF.REC.1400.244

## Health conditions studied

### 1

#### Description of health condition studied

peri-implant keratinized tissue

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

width of keratinized tissue

#### Timepoint

At the beginning of the study (before the intervention) and 1, 3 and 6 months after surgery

#### Method of measurement

Compass and digital caliper

### 2

#### Description

thickness of keratinized tissue

#### Timepoint

At the beginning of the study (before the intervention) and 1, 3 and 6 months after surgery

#### Method of measurement

Endodontic file and digital caliper

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: de-epithelialization of the free gingival graft using diamond bur

### Category

Treatment - Surgery

2

### Description

Control group: de-epithelialization of the free gingival graft using surgical blade

### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Department of Periodontology, Dental School, Isfahan Branch, Islamic Azad University

#### Full name of responsible person

Nasim Maghamipour

#### Street address

Boulevard, Arghavanieh Street, Eastern Jey Street

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8155139998

#### Phone

+98 31 1535 4053

#### Email

maghamipour2013@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Research Vice- Chancellor of Islamic Azad University  
Isfahan Branch

#### Street address

Khorasgan Branch, Islamic Azad University, University  
Boulevard, Arghavanieh Street, Eastern Jey Street,  
Isfahan

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8155139998

#### Phone

+98 912 293 2462

#### Email

maghamipour2013@gmail.com

### Grant name

### Grant code / Reference number

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

No

### Title of funding source

Esfahan University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Nasim Maghamipour

#### Position

Resident of periodontics

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dentistry

#### Street address

Khorasgan Branch, Islamic Azad University, University  
Boulevard, Arghavanieh Street, Eastern Jey Street,  
Isfahan

#### City

Esfahan

#### Province

Isfahan

#### Postal code

8155139998

#### Phone

+98 31 1535 4053

#### Fax

#### Email

n.maghamipour@khuisf.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Islamic Azad University  
**Full name of responsible person**  
Nasim Maghamipour  
**Position**  
Resident of periodontics  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Khorasgan Branch, Islamic Azad University, University  
Boulevard, Arghavanieh Street, Eastern Jey Street,  
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**Province**  
Isfahan  
**Postal code**  
8155139998  
**Phone**  
+98 31 1535 4053  
**Fax**  
**Email**  
n.maghamipour@khuisf.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Nasim Maghamipour  
**Position**  
Resident of periodontics  
**Latest degree**  
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**Other areas of specialty/work**  
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**Fax**  
**Email**  
n.maghamipour@khuisf.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

The documentation for this study is available to other researchers. Available documents will include data related to all studied variables (except patients' personal information) and in the form of SPSS file.

### When the data will become available and for how long

3 months after printing the results

### To whom data/document is available

The information of this research can be shared with all academic researchers.

### Under which criteria data/document could be used

For research and clinical use

### From where data/document is obtainable

Ways of communication with the responsible researcher:  
Email: n.maghamipour@khuisf.ac.ir

### What processes are involved for a request to access data/document

En After coordination with the responsible researcher, the requested data will be sent within one month.

### Comments