

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of Free Gingival Graft and Palatal Pedicle Graft Technique in peri-implant soft tissue phenotype modification in patients with implants in upper jaw

#### Protocol summary

##### Study aim

Determine the dimensional changes of soft tissue around the implant following free gingival graft and palatal pedicle graft.

##### Design

Randomized clinical trial, Parallel group, Triple blind, sealed envelope randomization.

##### Settings and conduct

Tehran dental school, triple blind, palatal pedicle and free gingival graft.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients aging over 18. 2. Patients Should be healthy (no periodontal and systemic problem.) 3. Patients should have stable implants. 4. Patients should have adequate thickness of palate (2mm) for harvesting. 5. Patients with keratinized tissue width deficiency around implant. Exclusion criteria: 1. Patient with history of radiotherapy and periodontitis. 2. Pregnant and patients smoking more than 10 cigarette each day. 3. Using any drugs which affects periodontal tissue or wound healing. 4. Patients with a history of soft tissue management in desired area.

##### Intervention groups

Intervention group: In this group, the graft is harvested from the palate adjacent to the implant area and fixed in the vicinity of the implant. Control Group: In this group, the free gingival graft is harvested from the palate and fixed in the vicinity of the implant.

##### Main outcome variables

Surface Shrinkage Keratinized tissue width Vestibular Depth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221226056930N1**

Registration date: **2023-03-18, 1401/12/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-18, 1401/12/27**

Update count: **0**

##### Registration date

2023-03-18, 1401/12/27

##### Registrant information

###### Name

Hossein Khoshkhou Titkanlou

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 4722 9054

###### Email address

burntgeneration74@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-20, 1401/12/01

##### Expected recruitment end date

2023-04-18, 1402/01/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Free Gingival Graft and Palatal Pedicle Graft Technique in peri-implant soft tissue phenotype modification in patients with implants in upper jaw

## Public title

Evaluation of two techniques of free gingival graft and palatal pedicle graft in soft tissue around the implant.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

1.patients age over 18 years old. 2.Healthy in systemic and periodontal condition. 3.patients with stable implants 4. patients with adequate thickness of palate for graft harvesting. 5.patients with keratinized tissue width deficiency.

### Exclusion criteria:

patients with history of radiotherapy or periodontitis.2. pregnant women or patients with a history more than 10-cigarrete smoking per day.3.patients who are undertreatment of drugs affecting periodontal tissue and wound healing.4.patients with a history of soft tissue grafting in site of surgery

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **34**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Individual randomization; Sealed envelope; The name of the surgical procedure is written on a sealed envelope and then on the day of surgery one of the envelopes is opened and the surgery is performed accordingly. Participants ,researchers and Data Safety Monitoring Board personals were blind to the study.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

The participants were blinded by the knowledge that they were participating in a research study, and the researcher and statistical analyzer are blind to the type of surgical technique performed for each patient.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Room6202, Enqelab Dormitory, Martyr Borhani alley, Martyr Hamidreza Hosseinalipour alley, Enqelab square, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417933486

#### Approval date

2022-08-24, 1401/06/02

#### Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1401.079

## Health conditions studied

### 1

#### Description of health condition studied

Comparison of free gingival graft and palatal pedicle graft

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Keratinized tissue width

#### Timepoint

Before intervention, 1month, 3month.

#### Method of measurement

University of North California-15 probe.

## Secondary outcomes

### 1

#### Description

Soft tissue surface shrinkage around implant.

#### Timepoint

Before intervention, 1month after intervention, 3months after intervention.

#### Method of measurement

Image j software.

### 2

#### Description

Vestibular depth changes.

#### Timepoint

Before intervention, 1month after intervention, 3months after intervention.

**Method of measurement**

University of North California-15 probe.

**3**

**Description**

Numeric analogue scale.

**Timepoint**

Before intervention, 1month after intervention, 3months after intervention.

**Method of measurement**

Likert scale.

**4**

**Description**

Amount of the analgesic pill used.

**Timepoint**

Before intervention, 1month after intervention, 3months after intervention.

**Method of measurement**

Note in the postoperative form provided to the patient.

**Intervention groups**

**1**

**Description**

Intervention group: Palatal pedicle graft.

**Category**

Treatment - Surgery

**2**

**Description**

Control group: Free gingival graft.

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Dental school, Tehran university of medical sciences.

**Full name of responsible person**

Hossein Khoshkhou Titkanlou

**Street address**

Room6202, Enqelab Dormitory, Martyr Borhani alley, Martyr Hamidreza Hosseinalipour alley, Enqelab square, Tehran, Iran.

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**Province**

Tehran

**Postal code**

1417933486

**Phone**

+98 915 219 8011

**Email**

burntgeneration74@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

حسین خوشخو تیتکانلو

**Street address**

Room6202, Enqelab Dormitory, Martyr Borhani alley, Martyr Hamidreza Hosseinalipour alley, Enqelab square, Tehran, Iran.

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Khoshkhou Titkanlou

**Position**

Resident

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Khoshkhou Titkanlou

**Position**

Resident

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dentistry

**Street address**

Room6202, Enqelab dormitory, Martyr Borhani alley,  
North Kargar street, Enqelab square, Tehran, Iran.

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**Province**

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1417933486

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+98 915 219 8011

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## Person responsible for updating data

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Khoshkhou Titkanlou

**Position**

Resident

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available