

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Evaluation the effect of using Acellular Dermal Matrix with or without strip auto gingival graft based on color and texture of keratinized gingiva.

#### Protocol summary

##### Study aim

A comparative study of the clinical conditions of color and texture of gingiva after transplantation by the acellular dermal matrix (ADM) and a narrow free gingiva strip with ADM alone.

##### Design

This study is a split-mouth randomized controlled clinical trial. 8 patients are enrolled with entry criteria. On cases, each half-jaw was randomized in the test group (Acellular dermal matrix and autogenous free gingival strip) or in the control group (Acellular dermal matrix).

##### Settings and conduct

This research is done at the Faculty of Dentistry, Islamic Azad University, Tehran. . In the control group, ADM was fixed at 7 mm wide, and in the test group, the coronal region of receptor site was covered up to marginal region by Acellular dermal matrix with a width of 5 mm and free gingival strip was made up to a width of 2 mm and placed in the apical region of the receptor site.

##### Participants/Inclusion and exclusion criteria

Entry requirements: A patient has one to two teeth on each mandibular side with insufficient keratinized tissue (1 mm or less). The patient has no diagnosed systemic disease with effect on periodontal tissues. Conditions of non-arrival: Patients have lack of entry criteria and non-compliance with essential follow-ups.

##### Intervention groups

The following measurements will be made on the facial surface of each tooth including the width of attached gingiva (AT) , the width of keratinized gingiva (KT) and the pocket depth(PD) on all people entering the study .

##### Main outcome variables

Keratinized gingiva width ,Attached gingiva width, probe depth, Shrinkage percentage and color of gingiva.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180714040460N6**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **retrospective**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

##### Registration date

2020-02-01, 1398/11/12

##### Registrant information

##### Name

Nima Nadafpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2256 4571

##### Email address

n\_nadaf@dentaliau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-05, 1398/08/14

##### Expected recruitment end date

2019-12-05, 1398/09/14

##### Actual recruitment start date

2019-11-08, 1398/08/17

##### Actual recruitment end date

2019-12-20, 1398/09/29

##### Trial completion date

2019-12-21, 1398/09/30

## Scientific title

Evaluation the effect of using Acellular Dermal Matrix with or without strip auto gingival graft based on color and texture of keratinized gingiva.

## Public title

Evaluation the effect of using Acellular Dermal Matrix with or without strip auto gingival graft based on esthetic and formation of keratinized gingiva.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

The patient should have one to two teeth on each mandibular or maxillary side with insufficient keratinized tissue (1 mm or less). The patient should not have systemic disease diagnosed with effects on periodontal tissues.

### Exclusion criteria:

The patient that does not want to cooperate on the project . The patient does not have ability of sufficient plaque control.

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **8**

Actual sample size reached: **8**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Blocked randomisation

## Blinding (investigator's opinion)

Double blinded

## Blinding description

All individuals involved in this research, such as clinicians, outcome evaluators, data analyzers, have been unaware of the randomization process of cases, and only researchers and operators in this study are aware of the allocation groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

The division of samples into two groups test and control was based on the type of graft technique.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Faculty of Dentistry Islamic Azad University, Tehran Branch

##### Street address

NO.9 , 9th Neyestan alley , Pasdaran Street , Tehran , Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

19585175

##### Approval date

2019-11-02, 1398/08/11

##### Ethics committee reference number

IR.IAU.DENTAL.REC.1398.042

## Health conditions studied

### 1

#### Description of health condition studied

The color of gingiva and the amount of keratinized gingiva after gingival graft surgery

##### ICD-10 code

##### ICD-10 code description

## Primary outcomes

### 1

#### Description

Loe and Silness plaque index

#### Timepoint

At the beginning and 6 months

#### Method of measurement

Observation

### 2

#### Description

Keratinized gingiva width

#### Timepoint

At the beginning and 6 months

#### Method of measurement

Observation and periodontal probe

### 3

#### Description

Attached gingiva width

#### Timepoint

At the beginning and 6 months

#### Method of measurement

Observation and periodontal probe

#### 4

**Description**

Probing depth

**Timepoint**

At the beginning and 6 months

**Method of measurement**

Observation and periodontal probe

#### 5

**Description**

Color

**Timepoint**

6 months

**Method of measurement**

Observation

#### 6

**Description**

Shrinkage percentage

**Timepoint**

6 months

**Method of measurement**

Observation and periodontal probe

### Secondary outcomes

#### 1

**Description**

Function and patients convenience

**Timepoint**

6 months

**Method of measurement**

Question

### Intervention groups

#### 1

**Description**

Intervention group: In the cases, each half-jaw was randomly assigned to the test group (the simultaneous use of the acellular dermal matrix and autogenous free gingival strap). In this group, the coronal region of receptor site was covered up to marginal margin by acellular dermal matrix with the trade name of Ceno Bone from the Ceno Biologics factory with a width of 5 mm and free gingival strap was made up to a width of 2 mm from the palate and placed in the apical region of the receptor site.

**Category**

Treatment - Surgery

#### 2

**Description**

Control group: In the cases, each half-jaw was randomly assigned to the control group (Acellular Dermal Matrix alone). In this group, the acellular dermal Matrix with trade name of Ceno Bone by the Ceno Biologics factory

will be fixed at 7 mm width in the recipient area with the polyamide thread 5.0.

**Category**

Treatment - Surgery

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Faculty of Dentistry Islamic Azad University of Tehran

**Full name of responsible person**

Nima Nadaf pour

**Street address**

No 9, 9th Neyestan Alley, Pasdaran Street, Tehran, Iran

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### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Arash Azizi

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No.9 , 9th Neyestan Alley , Pasdaran Street , 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**

Islamic Azad University

**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**  
Nima Nadaf Pour  
**Position**  
Periodontics assistant professor  
**Latest degree**  
Specialist  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Evaluation of the effect of Acellular Dermal Matrix with or without strip auto gingival graft on color and texture of keratinized gingiva in patients referring to the dental unit of Islamic Azad University of Tehran in 1397-1398 .

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

6 months after printing the results

### To whom data/document is available

All people who need data

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

The analyses that do not damage the outcome of our data analysis are allowed.

**From where data/document is obtainable**

Faculty of Dentistry Islamic Azad University of Tehran

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

Visit the Faculty of Dentistry, Islamic Azad University of Tehran and request there, and will access the data within 1 week.

**Comments**