

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)

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+98 21 2256 4571

Email address

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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

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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

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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
Other areas of specialty/work
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Person responsible for updating data

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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