Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Evaluation of using Acellular dermal matrix (ADM) and autogenous free gingival strap on clinical conditions of gingiva

Protocol summary

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

Design
This study is a split-mouth randomized controlled clinical trial. 11 patients are enrolled with entry criteria. On cases, each half-jaw was randomized in the test group (Acellular dermal matrix and autogenous free gingival strap) 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 margin by Acellular dermal matrix 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.

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 systemic disease diagnosed with effect on periodontal tissues. Conditions of non-arrival: Patients lacking 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 ,Attached gingiva width, probe depth, Shrinkage percentage.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180714040460N4**
Registration date: **2019-06-15, 1398/03/25**
Registration timing: **retrospective**

Last update: **2019-06-15, 1398/03/25**
Update count: **0**

Registration date
2019-06-15, 1398/03/25

Registrant information

Name
Nima Nadafpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
2018-11-07, 1397/08/16

Actual recruitment end date
2019-02-13, 1397/11/24

Trial completion date
2019-05-14, 1398/02/24

Scientific title
Evaluation of using Acellular dermal matrix (ADM) and autogenous free gingival strap on clinical conditions of gingiva

Public title
The effect of simultaneous use of Acellular dermal matrix and autogenous free gingival strap on formation of keratinized gingiva
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient should have one to two teeth on each mandibular 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 with poor oral hygiene .
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **11**
Actual sample size reached: **11**
Randomization (investigator's opinion)
Randomized
Randomization description
Divide the samples (each jaw) completely randomly into two groups of case and control by dropping the coin and dividing it into two groups of alloderm (control) and alloderm and autogenous free gingival strap (case)
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
Pasdaran Street, Ninth Neyestan Avenue
City
Tehran
Province
Tehran
Postal code
19585175
Approval date
2018-10-13, 1397/07/21
Ethics committee reference number
IR.IAU.DENTAL.REC.1397.032

Health conditions studied

1

Description of health condition studied
Insufficient keratinized gingiva
ICD-10 code
K06.0
ICD-10 code description
Gingival recession

Primary outcomes

1

Description
Loe and Silness plaque index
Timepoint
At the begining and 3 months
Method of measurement
Observation

2

Description
Loe and Silness gingival index
Timepoint
At the begining and 3 months
Method of measurement
Observation and probing

3

Description
Keratinized gingiva width
Timepoint
At the begining and 3 months
Method of measurement
Periodontal probe

4

Description
Attached gingiva width

Timepoint
At the begining and 3 months
Method of measurement
Periodontal probe

5

Description
Probing depth
Timepoint
At the begining and 3 months
Method of measurement
Periodontal probe

6

Description
Shrinkage percentage
Timepoint
3 months
Method of measurement
Periodontal probe

Secondary outcomes

empty

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 called 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 called 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
Tehran, Pasdaran Street, Ninth Neyestan Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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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 using Acellular dermal matrix (ADM) and autogenous free gingival strap on clinical conditions of 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
Analyzes 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