

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The Comparison of Acellular Dermal Matrix Allograft (CenoDerm) and a Subepithelial Connective Tissue Graft for the Treatment of Gingival Recession.

Protocol summary

Summary

Gingival Recession may lead to increase in dental sensitivity, pain, hardship of oral hygienic activities, root cavity, inappropriate gingival appearance, as well as missing periodontal connections. There are various treatment methods for root coverage. Acellular dermal grafts, although being of the high cost of Subepithelial Connective Tissue, is applied, because of its numerous advantages, especially in young people, old ages, and also the patients who are not able to have vast operations on, because of their systemic diseases. The present research aims at clinically comparing the Acellular Dermal Matrix Allograft (CenoDerm) along with Subepithelial Connective Tissue Graft, is used for the Treatment of Gingival Recession. There were twelve patients referred to the periodontics department of Babol Dentistry School in order to treat two-sided individual gingival recession. They will be selected according to the entry criteria (enough Vestibule depth, etc.), exclusion (pregnancy, etc.). The area to be operated on would be randomly divided into two parts in each person (totally 24 areas). One part would be treated through Transport Coronal flap with connective tissue graft placement method [CPF (coronally positioned flap) + CTG (Connective Tissue Graft)] and the other part by Acellular Dermal Matrix Allograft (Ceno-Derm) (manufactured by replicating tissues Creed) and coronal displacement of the flap can be treated. All the surgeries are done by one person. Afterwards, during the surgery and intervals of one, three, and six months, the variables would be recorded by another one. In all the sessions of measuring the variables, clinical photography is done. The statistical data would be measured through SPSS. Moreover, in order to analyze the variables, the Wilcoxon Signed Rank Test as well as the Mann-Whitney Test will be applied

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305201760N23**

Registration date: **2013-08-23, 1392/06/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-23, 1392/06/01

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 11 3236 2282

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Recruitment status

Recruitment complete

Funding source

Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Acellular Dermal Matrix Allograft (CenoDerm) and a Subepithelial Connective Tissue Graft for the Treatment of Gingival Recession.

Public title

The Comparison of Acellular Dermal Matrix Allograft (CenoDerm) and a Subepithelial Connective Tissue Graft for the Treatment of Gingival Recession.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Analysis of single-sided facial tissue depth of $2\text{mm} \leq X$ CEJ in teeth or premolars; All sub-group analyzes of Miller class I / II; Selected teeth without fillings and no bleeding after probing; Persons 18 years and older; Ability to maintain good oral hygiene (% 20 O'Leary plaque score $\leq$); Vestibule depth of enough. Exclusion criteria: Pregnancy; use of drugs interfering with wound healing (corticosteroids, anti-cancer), or medicines that may cause gingival enlargement; Smoking; which prohibits any local or systemic disease, periodontal surgery is prescribed; Traumatic brushing methods; Hard toothbrushes or toothpaste abrasives; History of periodontal surgery in the past 2 years; The use of removable prosthodontic or orthodontic appliances in the area.

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

4

Groups that have been masked*No information***Sample size**Target sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Babol University of Medical Sciences

Street address

Ganjafoz Road, Babol University of Medical Sciences

City

Babol

Postal code**Approval date**

2013-05-14, 1392/02/24

Ethics committee reference number

2458

Health conditions studied**1****Description of health condition studied**

Gingival recession

ICD-10 code

K06.0

ICD-10 code description

Gingival recession

Primary outcomes**1****Description**

Treatment of Gingival Recession.

Timepoint

1 month, 3 months, 6 months after surgery.

Method of measurement

Clinical photography

Secondary outcomes**1****Description**

Clinical attachment level

Timepoint

1 month, 3 months, 6 months after surgery

Method of measurement

Clinical (in mm)

2**Description**

Probing depth

Timepoint

1 month, 3 months, 6 months after surgery

Method of measurement

Clinical (in mm)

3**Description**

Gingival thickness

Timepoint

1 month, 3 months, 6 months after surgery

Method of measurement

Clinical (in mm)

4**Description**

Mgj distance to CEJ

Timepoint

1 month, 3 months, 6 months after surgery

Method of measurement

Clinical (in mm)

5**Description**

Vertical recession depth (VRD)

Timepoint

1 month, 3 months, 6 months after surgery

Method of measurement

Clinical (in mm)

6**Description**

Healing

Timepoint

1 month, 3 months, 6 months after surgery

Method of measurement

Landry Index

7**Description**

Cosmetic results

Timepoint

1 month, 3 months, 6 months after surgery

Method of measurement

Aesthetic Index (VAS)

8**Description**

Discomfort after surgery

Timepoint

1 month, 3 months, 6 months after surgery

Method of measurement

Indexed pain (VAS)

Intervention groups**1****Description**

Control group: Transport Coronal flap with connective tissue graft placement method is treated [CPF(coronally positioned flap) + CTG(Connective Tissue Graft)]

Category

Treatment - Surgery

2**Description**

Intervention group: With Acellular dermal matrix allograft (CenoDerm) (manufactured by replicating tissues Creed) and coronal displacement of the flap can be treated. [ADMA(Acellular Dermal Matrix Allograft)+CPF(coronally positioned flap)]

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental colleges of Babol

Full name of responsible person

Dr. Masoomah Haghpanah Aski

Street address

Dental Colleges of Babol

City

Babol

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Ganjafroz Avenue

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Babol

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dental College of Babol

Full name of responsible person

Dr. Masoomeh Haghpanah Aski

Position

Postgraduate Periodontics

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Name of organization / entity

Fatemehzahra Infertility & Reproductive Health
Research Center

Full name of responsible person

Nargess Gholizadeh Pasha

Position

M.A/Responsible of Reseach Center

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Person responsible for scientific inquiries

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Dental College of Babol

Full name of responsible person

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Position

Periodontics

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty