Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The evaluation of using Acellular Dermal Matrix Allograft (CenoDerm) together with plasma rich in growth factor in gingival augmentation

Protocol summary

Summary

The present study aimed at evaluation of using Acellular Dermal Matrix Allograft (CenoDerm®) together with plasma rich in growth factor (PRGF) in gingival augmentation. In this split mouth double blinded randomized controlled trial study, 10 patients (referring to Periodontics department of Babol university of medical sciences, dental faculty) will be included based on inclusion (At least 18 years of age; no systemic disease and etc.) and exclusion criteria (Smoking; Pregnancy and etc.). Tooth selection as intervention and control group for each patient will be done randomly. The technique using in intervention and control groups will be exactly the same. The only difference will be in rehydration liquid that is PRGF in the intervention group but normal saline in control group. Cenoderm® will be rehydrated in normal saline or PRGF for 20 minutes before using in surgical site. Primary outcomes in this study are: width of Keratinized gingiva and wound healing index (will be assessed in 3rd, 7th, 10th, 14th days and one and three months follow ups). Secondary outcomes are thickness of gingiva (will be assessed before surgery and one and three months after surgery) and pain index (will be assessed in 1st, 2nd, 3rd and 7th days after surgery)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503261760N38**
Registration date: **2015-04-28, 1394/02/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-28, 1394/02/08

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

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

Country

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of using Acellular Dermal Matrix Allograft (CenoDerm) together with plasma rich in growth factor in gingival augmentation

Public title

The evaluation of using Acellular Dermal Matrix Allograft (CenoDerm) together with plasma rich in growth factor in gingival augmentation

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: At least 18 years of age; The sound system; The plaque before transplantation, 25% or less; Deficient gingival bilaterally Exclusion criteria: Smoking; Pregnancy; There occlusal trauma; Surgical procedures were performed in the desired area in the last 12 months; Oral mucosal disease; There are more than 3 mm region of the envelope with the link; Periapical lesion; Beyond tooth mobility grade 1; Affecting periodontal medication (eg, phenytoin, oral contraceptives, estrogen and progesterone compounds, of activities and cyclosporine)
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The study of the patient and the sampler is a double-blind clinical trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical sciences
Street address
Babol University of Medical Sciences, Ganjafroz Avenu
City
Babol
Postal code
Approval date
2014-10-12, 1393/07/20
Ethics committee reference number
4709

Health conditions studied

1

Description of health condition studied
Lack of attached gingival
ICD-10 code
K06
ICD-10 code description
Other disorders of gingiva and edentulous alveolar ridge

2

Description of health condition studied
Healing
ICD-10 code
S00.5
ICD-10 code description
Superficial injury of lip and oral cavity

Primary outcomes

1

Description
Width of keratinized gingival
Timepoint
Before surgery and one and three months after surgery
Method of measurement
Probe Williams with compass and caliper as well as the roll test

2

Description
Healing index
Timepoint
Day three, seven, ten and fourteen, and one month and three months after surgery
Method of measurement
Landry Healing index

Secondary outcomes

1

Description
Pain Index
Timepoint
Before surgery and one and three months after surgery
Method of measurement
Visual Analogue Scale

2

Description
Gingiva thickness
Timepoint
Before surgery and one and three months after surgery.
Method of measurement
Williams probe

Intervention groups

1

Description
Intervention Group:The only difference will be in rehydration liquid that is PRGF in the intervention group
Category
Treatment - Drugs

2

Description
Control Group: The thickness of Cenoderm® will be 1.5 mm. In the control group of normal saline rehydration will be done.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental colleges of Babol, Babol University of Medical Sciences
Full name of responsible person
Dr. Pasha Ghahari
Street address
Babol University of Medical Sciences, Gangafroz Avenue
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
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 colleges of Babol
Full name of responsible person
Dr. Pasha Ghahari
Position
Post graduate student of periodontology
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Nargess Gholizadeh Pasha
Position
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Other areas of specialty/work

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00

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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