

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

Iran (Islamic Republic of)

##### Phone

+98 11 3236 2282

##### Email address

zahra@mubabol.ac.ir

#### 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**

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**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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**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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**Web page address****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*