

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Study of the effect of plasma rich in growth factors with tunnel technique in the treatment of gingival recession

#### Protocol summary

##### Study aim

Study the effect of plasma rich in growth factors with tunnel technique in the treatment of gingival recession

##### Design

Clinical trials with a control group, with parallel groups, double-blind, randomized. Surgical areas are randomly divided into two groups by coin throwing method.

##### Settings and conduct

The study will be conducted on patients referring to the periodontics department of Babol Dental School, which has a bilateral gingival recession. Sampling was done randomly and for each treatment group, 10 samples and a total of 20 samples were considered. Participants and outcome measurer of this study are blind (double-blind).

##### Participants/Inclusion and exclusion criteria

Selection criteria: At least 18 years old, The presence of single-ended gingival recession, alive teeth (The confounding factor is as low as possible), without filling or bleeding of probing, Keratinized gum width greater than 2mm, Signature of consent form; exclusion criteria: Pregnancy, Coagulation problems, Any local or systemic disease that has a contraindication to periodontal treatment. Active infectious disease, smoking, the Fernum stretch in the surgical area, Use of traumatic brushing techniques.

##### Intervention groups

1. Debridement with applying PRGF, 2. Debridement alone

##### Main outcome variables

Clinical parameters include keratinized tissue width, clinical attachment level, clinical probing depth, the vertical depth of the gingival recession, recession width, CEJ to MGJ distance, root coverage percentage, healing index, esthetic visual analogue scale, and pain visual analogue scale.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20100427003813N9**

Registration date: **2018-10-02, 1397/07/10**

Registration timing: **retrospective**

Last update: **2018-10-02, 1397/07/10**

Update count: **0**

#### Registration date

2018-10-02, 1397/07/10

#### Registrant information

##### Name

Niloofar Jenabian

##### Name of organization / entity

Dental Faculty of University of Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1229 1408

##### Email address

n.jenabian@mubabol.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-04-21, 1397/02/01

#### Expected recruitment end date

2018-06-22, 1397/04/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Study of the effect of plasma rich in growth factors with tunnel technique in the treatment of gingival recession

## Public title

Study of the effect of plasma rich in growth factors with tunnel technique in the treatment of gingival recession

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

At least 18 years old The presence of single-ended gingival recession of the miller class I / II with a depth of 2 mm = <CEG of the anterior and permoral teeth alive teeth, without filling or bleeding of probing (The confounding factor is as low as possible) Ability to maintain proper sanitation(O'LEARY plaque score<=20%) Keratinized gum width greater than 2mm Gingival thickness 0.5 = <2mm apical gum margin Signature of consent form

### Exclusion criteria:

Pregnancy Coagulation problems Use medications of Platelet Interaction (NSAIDs) Use of drugs which interact with wound healing Any local or systemic disease that has a contraindication to periodontal treatment. Allergy to surgical materials (The confounding factor is as low as possible) Active infectious disease (hepatitis, tuberculosis and AIDS) smoking Fernum stretch in the surgical area Use of traumatic brushing techniques, toothbrushes and abrasive toothbrushes Use of removable prosthesis plaques in the desired area

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each side of the mouth is considered as a sample.

## Randomization (investigator's opinion)

Randomized

## Randomization description

Surgical areas are randomly divided into two groups by coin throwing method

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients are unaware of which treatment group they are. The outcome measurer is different from whom that cures patients.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol univercity of medical science

##### Street address

Ganjafrooz Ave.

##### City

Babol

##### Province

Mazandaran

##### Postal code

4717647745

#### Approval date

2018-02-26, 1396/12/07

#### Ethics committee reference number

MUBABOL.HRI.REC.1396.210

## 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

Keratinized tissue width

#### Timepoint

before surgery, 6 weeks and 3 months after surgery

#### Method of measurement

with periodontal probe

### 2

#### Description

Clinical attachment level

#### Timepoint

before surgery, 6 weeks and 3 months after surgery

#### Method of measurement

with periodontal probe

### 3

#### Description

Recession width

#### Timepoint

before surgery, 2 weeks and 3 months after surgery

**Method of measurement**

with periodontal probe

**4****Description**

Vertical Recession Depth

**Timepoint**

before surgery, 2 weeks and 3 months after surgery

**Method of measurement**

with periodontal probe

**5****Description**

Healing index

**Timepoint**

1 and 3 days 1 week and 1 months after surgery

**Method of measurement**

with healing index (HI) based on Landry index

**6****Description**

Clinical Probing Depth

**Timepoint**

before surgery, 6 weeks, 3 months after surgery

**Method of measurement**

with periodontal probe

**7****Description**

Esthetic Visual Analogue scale

**Timepoint**

before surgery, 6 weeks, 3 months after surgery

**Method of measurement**

with Visual analogue scale

**8****Description**

Pain Visual Analogue scale

**Timepoint**

1, 3 and 7 days after surgery

**Method of measurement**

whit Visual analogue scale

**9****Description**

Distance from cementoamel junction (CEJ) to mucogingival junction (MGJ or MGJL) in the middle of the buccal surface of the tooth

**Timepoint**

before surgery, 6 weeks, 3 months after surgery

**Method of measurement**

with periodontal probe

**10****Description**

Percentage of Root Coverage

**Timepoint**

3 months after surgery

**Method of measurement**

[(Vertical Recession Depth before surgery - Vertical Recession Depth after Surgery)/ divided Vertical Recession Depth before surgery]\*100

**Secondary outcomes**

empty

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

Intervention group: open flap debridement with plasma-rich growth factor

**Category**

Treatment - Surgery

**2****Description**

Control group: Open flap debridement

**Category**

Treatment - Surgery

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

Periodontology departmet of Babol dental faculty

**Full name of responsible person**

Fatemeh Ahrari

**Street address**

Ganjafrooz Ave.

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3220 7918

**Email**

Dr\_mahtab\_777@yahoo.com

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

Babol University of Medical Sciences

**Full name of responsible person**

Niloofer Jenabian

**Street address**

Ganjafrooz Ave.

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3220 7918

**Email**

n.jenabian@mubabol.ac.ir

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

Yes

**Title of funding source**

Babol University of Medical Sciences

**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**

Babol University of Medical Sciences

**Full name of responsible person**

Niloofer Jenabian

**Position**

Associated professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Ganjafrooz Ave.

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3220 7918

**Email**

n.jenabian@mubabol.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Niloofer Jenabian

**Position**

Associated professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Ganjafrooz Ave.

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3220 7918

**Email**

n.jenabian@mubabol.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh Ahrari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Ganjafrooz Ave.

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Phone**

+98 11 3220 7918

**Email**

Dr\_mahtab\_777@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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