

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)

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+98 11 1229 1408

Email address

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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

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

Babol University of Medical Sciences

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

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

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Position

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Latest degree

Specialist

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

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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