Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of plasma rich in growth factors (PRGF) with sub-epithelial connective tissue graft via semilunar technique in dark triangle treatment

Protocol summary

Study aim

Evaluation of the effect of plasma rich in growth factors (PRGF) with sub- epithelial connective tissue graft via semilunar technique in dark triangle treatment

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 dark triangle. Sampling will be done randomly and for each treatment group, 16 samples and a total of 32 region will be considered. Participants and outcome measurer of this study will be blind (double-blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, At least one region of an absence of papilla should be sub-type I, II of Tarnow's classification and in the Anterior Maxilla, Ability to maintain proper good oral hygiene (O'LEARY plaque score<=20%), Signature of a consent form. Exclusion criteria: Pregnancy, Coagulation problems, Medications interfering with Platelet function (NSAIDs), Medications interfering with wound healing (Corticosteroid, anti-cancer), Any systemic or local disease that has a contraindication in periodontal treatment, Allergic reaction to materials used in surgery, Active infectious disease (hepatitis, tuberculosis and AIDS), smoking, Frenum stretch in the surgical area, Orthodontic patients, The use of medications that are well-established causes of gingival enlargement.

Intervention groups

Intervention group: Connective tissue graft with PRGF via Semilunar technique

Main outcome variables

Healing index, probing pocket depth (PPD), Esthetic Visual Analogue scale, Postoperative pain, Bleeding on probing (BOP) and Mesiodistal and Apicocoronal distance of the dark triangle.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100427003813N11**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-29, 1399/01/10**
Update count: **0**

Registration date

2020-03-29, 1399/01/10

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-15, 1398/10/25

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of plasma rich in growth factors (PRGF) with sub- epithelial connective tissue graft via semilunar technique in dark triangle treatment

Public title

Evaluation of the effect of plasma rich in growth factors (PRGF) with sub- epithelial connective tissue graft via semilunar technique in dark triangle treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years At least one region of an absence of papilla should be sub-type I, II of Tarnow's classification and in the Anterior Maxilla Ability to maintain proper good oral hygiene (O'LEARY plaque score<=20%) Signature of consent form

Exclusion criteria:

Pregnancy Coagulation problems Medications interfering with Platelet function (NSAIDs) Medications interfering with wound healing (Corticosteroid, anti-cancer) Any systemic or local disease that has a contraindication in periodontal treatment Allergic reaction to materials used in surgery Active infectious disease (hepatitis, tuberculosis and AIDS) smoking Frenum stretch in the surgical area Orthodontic patients The use of medications that are well-established causes of gingival enlargement Use of traumatic tooth brushing, abrasive tooth brushes Use of antibiotics in the past 3 months (for 2 weeks) Periodontal disease

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **16**

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

Patients will be enter the study according to inclusion and exclusion criteria. 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

2020-01-11, 1398/10/21

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.266

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

Healing index

Timepoint

On the day of surgery, 14, 30, 90, and 180 days after the surgery

Method of measurement

with healing index (HI) based on Landry index

2

Description

probing pocket depth (PPD)

Timepoint

On the day of surgery, 14, 30, 90, and 180 days after the

surgery

Method of measurement

using a standardized periodontal probe

3

Description

Esthetic Visual Analogue scale

Timepoint

On the day of surgery, 14, 30, 90, and 180 days after the surgery

Method of measurement

with Visual analogue scale

4

Description

Postoperative pain

Timepoint

On the day of surgery, 14, 30, 90, and 180 days after the surgery

Method of measurement

with Visual analogue scale

5

Description

Bleeding on probing (BOP)

Timepoint

On the day of surgery, 14, 30, 90, and 180 days after the surgery

Method of measurement

using a standardized periodontal probe

6

Description

Mesiodistal distance of dark triangle

Timepoint

On the day of surgery, 14, 30, 90, and 180 days after the surgery

Method of measurement

using a standardized periodontal probe

7

Description

Apicocoronal distance of the dark triangle

Timepoint

On the day of surgery, 14, 30, 90, and 180 days after the surgery

Method of measurement

using a standardized periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Connective tissue graft with PRGF via Semilunar technique

Category

Treatment - Surgery

2

Description

Control group: Connective tissue graft via Semilunar technique

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontology departmet of Babol dental faculty

Full name of responsible person

mahsa shirzad

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Ganjafrooz Ave.

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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
Niloofar Jenabian

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Position
Associate Professor

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Person responsible for updating data

Contact

Name of organization / entity
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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