

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Clinical evaluation of the efficacy of plasma rich in growth factors with connective tissue graft in treatment of gingival recession

Protocol summary

Summary

Placing the connective tissue graft under the epithelial flap holds the most promise for treatment of gingival recession. Therefore the aim of this study is to determine the efficacy of connective tissue graft in association with plasma rich in growth factors in treatment of gingival recession. Eleven patients are selected from the applicants of the periodontology part of Babol dental school according to the inclusion criteria (Miller class 1 and 2 of gingival recession) and exclusion criteria (smoker patients, patients who had history of periodontal surgery at the selected site). The patients randomly are divided into two treatment groups; Control group: treatment in one site with connective tissue graft (donor site: palatal region) and coronally advanced flap; Test group: treatment with connective tissue graft that has been applied with plasma rich in growth factors. Patients would not be informed of the surgery method in each side. The surgeries are performed by one surgeon and in one center. All the patients are instructed to rinse by chlorhexidine 0.2% for 4 weeks. Determining the width of keratinized gingiva, clinical probing depth, vertical recession depth, recession width and gingival thickness are performed at 1 and 6 month after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201168747N1**
Registration date: **2012-08-26, 1391/06/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-26, 1391/06/05

Registrant information

Name

Ehsan Zahedi

Name of organization / entity

Dental School, Babol

Country

Iran (Islamic Republic of)

Phone

+98 11 1229 7951

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the efficacy of plasma rich in growth factors with connective tissue graft in treatment of gingival recession

Public title

The effect of plasma rich in growth factors in treatment of gingival recession

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 1) The presence of either bilateral isolated or multiple facial defects with recession depths

≥2 mm when measured from the cemento-enamel junction at anterior teeth or premolars; 2) The defects that are judged as Miller Class I or Class II; 3) The selected teeth should be vital, free of restorations or had restorations removed, and with no bleeding upon probing; 4) The age of patients should be within 18 to 65; 5) Good oral hygiene (O'Leary plaque score ≤20%); 6) Width of keratinized gingiva should be <2 mm; 7) Gingival thickness should be >0.5mm. Exclusion criteria: 1) Smoking; 2) Any uncontrolled local or systemic disease that might contraindicate periodontal surgery; 3) Pregnancy; 4) Hematologic disorders; 5) Usage of the drugs that have intervention with wound healing (corticosteroid, chemotherapeutic agents); 6) Usage of the drugs that have intervention with platelet aggregation; 7) Allergy to tetracycline; 8) Traumatic methods of tooth brushing; 9) Applying abrasive dentifrices; 10) Applying removable partial denture; 11) The history of periodontal surgery at the selected site.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethics committee of Babol University of Medical Sciences

Street address

Ethics committee of Babol University of Medical Sciences, No.2, Gangafruz Avenue

City

Babol

Postal code

4717641367

Approval date

2012-01-05, 1390/10/15

Ethics committee reference number

30/5337/ز/پ

Health conditions studied**1****Description of health condition studied**

Gingival Recession

ICD-10 code

k06.0

ICD-10 code description

Gingival recession (generalized)(localized)(post-infective)(post-operative)

Primary outcomes**1****Description**

Gingival recession

Timepoint

Six month after surgery

Method of measurement

Clinical examination

Secondary outcomes**1****Description**

Width of keratinized gingiva

Timepoint

Baseline, 1 and 6 month after surgery

Method of measurement

Clinical examination

2**Description**

Clinical attachment level

Timepoint

Baseline, 1 and 6 month after surgery

Method of measurement

Clinical examination

3**Description**

Clinical probing depth

Timepoint

Baseline, 1 and 6 month after surgery

Method of measurement

Clinical examination

4**Description**

Vertical depth of gingival recession

Timepoint

Baseline, 1 and 6 month after surgery

Method of measurement

Clinical examination

5

Description

Width of gingival recession

Timepoint

Baseline, 1 and 6 month after surgery

Method of measurement

Clinical examination

6

Description

Gingival thickness

Timepoint

Baseline, 1 and 6 month after surgery

Method of measurement

Clinical examination

7

Description

Gingival index

Timepoint

Baseline, 1 and 6 month after surgery

Method of measurement

Clinical examination

8

Description

The distance between mucogingival junction and cementoenamel junction (Mgjl)

Timepoint

Baseline, 1 and 6 month after surgery

Method of measurement

Clinical examination

Intervention groups

1

Description

Control group: connective tissue graft with coronally flap advancement

Category

Treatment - Drugs

2

Description

Intervention group: Moistened connective tissue graft with plasma rich in growth factors and coronally advanced flap

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Dental School

Full name of responsible person

Ehsan Zahedi

Street address

Dental School, Babol University of Medical Sciences, No.2, Ganjafruz Avenue

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

No.2, Ganjafruz Avenue

City

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, 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

Babol Dental School

Full name of responsible person

Ehsan Zahedi

Position

Periodontics Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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