Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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 cementoenamel 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/پ/ژ

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
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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
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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, 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
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Person responsible for scientific inquiries

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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