

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of plasma rich growth factor in treatment of molar class II furcation involvement

Protocol summary

Summary

Molars furcation involvement is one of the most common Dentoalveolar problems and the plasma rich growth factors effect plays a role on regeneration of bony defect trend. Then the aim of this study is to determine the effect of plasma rich growth factor on treatment of molar class II furcation involvement. 12 patients are selected from the applicants of the periodontology part of dentistry university of Babol according to inclusion criteria (patients with moderate to severe chronic periodontitis that molar class II furcation...) and exclusion criteria (smoker patients, patients who need to antibiotic prophylaxis treatment...). The patients according to defect are divided to two treatment groups randomly. Control group: treatment in one site with double layer membrane biogidealone, test group: treatment with PRGF gel like in furcation area that cover with double layer biogide membrane. Stages of this study: oralhygiene education, complete scaling and root planning for achieving the ideal biofilm control and gingival health status, adjust occlusion if it is necessary and surgey treatment. Follow up after surgery will be done every week until 8 weeks, then once in a month until reentry surgery. If the combination treatment of PRGF and biogide is effective, we can use PRGF in improvement of regeneration process of Furcation involvement. The clinical parameter will be evaluated in the beginning of study and immediately before and during surgery and 1 and 6 month after surgery in environment of each teeth by reentry method. These parameters are recorded at the center of furcation. We anticipate that the PRGF is effective in molar, class II furcation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201231760N15**

Registration date: **2012-02-22, 1390/12/03**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2012-02-22, 1390/12/03

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 2282

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Recruitment status

Not enough for processing

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2011-08-23, 1390/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of plasma rich growth factor in treatment of molar class II furcation involvement

Public title

The effect of plasma rich growth factor in treatment of molar class II furcation involvement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients who have moderate to severe periodontitis that have class II furcation involvement in buccal or lingual first molar or second molar in mandible; good cooperation after the primary periodontal treatment; The horizontally amount to enter the probe is >3mm. Exclusion criteria: the patients who have systemic disease; the patients who need the prophylactic treatment of antibiotic for prevention of bacterial endocarditis; Smoker patient; the teeth that have anatomical complication like cervical enamel projection, bi furcation ridge concavity, accessory canal and mobility >class II; The patient who uses the drugs that interact with periodontal healing, prescience of caries and filling in furcation area and presence of contra indication for periodontal surgery; the teeth in clinical view or radiography has evidence of preapical pathology; and regarding to the test performance the patient before surgery if the bleeding time and CBC is abnormal.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 12

Randomization (investigator's opinion)

Randomized

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

Double 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

Babol University of Medical sciences, Gangafroz Avenue

City

Babol

Postal code

4717641367

Approval date

2012-01-17, 1390/10/27

Ethics committee reference number

5527

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

molar class II furcation involmment

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

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

treatment of molar class II furcation involvement

Timepoint

Six months after the start of the intervention

Method of measurement

Clinical examination

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

vertical probing depth(VPD)

Timepoint

Baseline and immediately before surgery and 1 month after surgery around each tooth

Method of measurement

Clinical examination

2**Description**

Vertical clinical att level(VCAL)

Timepoint

Baseline and immediately before surgery and 1 month after surgery around each tooth

Method of measurement

Clinical examination

3**Description**

Fonix to base of defect(FBD)

Timepoint

During the first surgery and 6 months after surgery to reentry around each tooth

Method of measurement

Clinical examination

4

Description

fonix to Alveolar crest(FAC)

Timepoint

During the first surgery and 6 months after surgery to reentry around each tooth

Method of measurement

Clinical examination

5

Description

Furcation vertical compoment (FVC)

Timepoint

During the first surgery and 6 months after surgery to reentry around each tooth

Method of measurement

Clinical examination

6

Description

Furcation horizontal component(FHC)

Timepoint

During the first surgery and 6 months after surgery to reentry around each tooth

Method of measurement

Clinical examination

Intervention groups

1

Description

Control group: in one site treatment with double layer of membrane alone the treatment interference with drug

Category

Treatment - Drugs

2

Description

Intervention group: Treatment with PRGF gel like in furcation area that is covered with double layer membrane of biogide.The preparation of PRGF gel: PRGF that 500 microliter in every tube is rich of growth factor and 4 times accumulated. Pour the Plasma in empty tube and for change it to gel to use it to apply space maintainer under the membrane.50 microliter with pipet 50 microliter from calcium chloride for every cc from PRGF add to sterile tube, after mixing plasma with calcium chloride, pour it into the sterile glassy dish and close its door.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Babol

Full name of responsible person

Hodis Ehsani

Street address

Dental School, Babol University of Medical Sciences, Ganjafroz Road

City

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

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Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Gangafroz 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 and Technology, 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**

Dental School, Babol

Full name of responsible person

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Position

student

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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