Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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: oralhygine 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)

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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 involvment
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, Ganjafruz Road
City
Babol

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
Street address
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
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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