Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical and radiographic evaluation of applying 1.2% Atorvastatin gel with plasma rich in growth factor (PRGF) for treatment of class II furcation involvement

Protocol summary

Study aim
Effect 1.2% Atorvastatin gel with plasma rich in growth factor (PRGF) for treatment of class II furcation involvement

Design
Randomized clinical trial, with control group, parallel design, double blind

Settings and conduct
Samples are selected according to the criteria of entry and exit from the Babol periodontal department of Dentistry in easy or accessible manner. The patients and the outcome assessor are not aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with moderate to severe chronic periodontitis with severe grade II furcation on the buccal or lingual side of the first or second mandibular molar, and the horizontally probing depth of the probe in the affected areas should be greater than or equal to 3mm. Exit criteria: Systemic disease, need for prophylactic antibiotics to prevent bacterial endocarditis, use of intermittent drugs with periodontal improvement, smoking, contraindication for periodontal surgery, anatomical complications such as accessory canal, CEP concavity, bifurcation ridge, There is evidence of periapical pathology in the clinical or radiographic profile of the tooth and the likelihood of unacceptable patient consent after the initial periodontal treatment of the patient.

Intervention groups
Use of Atorvastatin1.2% alone Use of Atorvastatin1.2% plus PRGF Use of PRGF alone Debridment alone

Main outcome variables
vertical probing depth vertical clinical attachment level gingival recession horizontal probing depth gingival index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100427003813N7**
Registration date: **2018-05-17, 1397/02/27**
Registration timing: **retrospective**

Last update: **2018-05-17, 1397/02/27**
Update count: **0**

Registration date
2018-05-17, 1397/02/27

Registrant information

Name
Niloofar Jenabian
Name of organization / entity
Dental Faculty of University of Babol University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-05-27, 1396/03/06

Expected recruitment end date
2017-07-27, 1396/05/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical and radiographic evaluation of applying 1.2% Atorvastatin gel with plasma rich in growth factor (PRGF) for treatment of class II furcation involvement

Public title
Clinical and radiographic evaluation of applying 1.2% Atorvastatin gel with plasma rich in growth factor (PRGF) for treatment of class II furcation involvement
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with moderate to severe chronic periodontitis with severe grade II fractures on the buccal or lingual side of the first or second mandibular molars The horizontal probing depth of the probes in the affected areas is greater than or equal to 3mm
Exclusion criteria:
Systemic disease The need for prophylactic antibiotics to prevent bacterial endocarditis Use of intermittent drugs with periodontal improvement smoking presence of contraindication for periodontal surgery dental anatomical complications such as accessory canal concavity CEP, bifurcation ridge Tooth mobility more than Grade II The presence of decay and filling in the area of forcation There is evidence of periapical pathology in the clinical or radiographic view of the tooth Possibility of unaccompanied consent after initial periodontal treatment
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **4**
First or second molar of right or left side of mandible
Actual sample size reached: **10**
More than 1 sample in each individual
Actual sample size in each individual: **4**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients are classified in the intervention group with knowledge of the entire study and informed consent form. The outcome elevator measures the study data without any knowledge about type of treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences, Dept. of Research and Technology
Street address
University of Medical Sciences, Dept. of Research and Technology Ganjafroz Ave, Babol
City
Babol
Province
Mazandaran
Postal code
4717641367
Approval date
2017-06-18, 1396/03/28
Ethics committee reference number
MUBABOL.REC.1396.25

Health conditions studied

1

Description of health condition studied
furcation grade 2 involvement of lower jaw molars
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
grade 2 furcation involvement of lower jaw molars
Timepoint
Immediately before surgery 3 and 6 months after surgery
Method of measurement
periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 1: Using Atorvastatin1.2% alone in treatment of 6 mandibular molar grade II furcation involvment

Category

Treatment - Surgery

2

Description

Intervention group 2: use of Atorvastatin1.2% plus PRGF in treating 6 mandibular molar grade II furcation involvment

Category

Treatment - Surgery

3

Description

Intervention group 3: Use of PRGF alone in treating 6 mandibular molar grade II furcation involvment

Category

Treatment - Surgery

4

Description

Control group: Debridement alone in treating 6 mandibular molar grade II furcation involvment

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Dental University

Full name of responsible person

Sakineh Mohammadpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Aliakbar Moghadamnia

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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 updating data

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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