

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 Atorvastatin 1.2% alone Use of Atorvastatin 1.2% plus PRGF Use of PRGF alone Debridement 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

Country

Iran (Islamic Republic of)

Phone

+98 11 1229 1408

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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 evaluator 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**

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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 involvement

Category

Treatment - Surgery

2

Description

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

Category

Treatment - Surgery

3

Description

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

Category

Treatment - Surgery

4

Description

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

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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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