

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Clinical and radiographic evaluation of applying Plasma rich growth factor(PRGF) with Metformin gel 1% in treating periodontal two-walls intrabony defects

Protocol summary

Study aim

Main goal: the effect of Plasma rich growth factor(PRGF) with Metformin gel 1% in treating periodontal two walls intrabony defects

Design

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

Settings and conduct

Periodontics department of Babol dentistry faculty with chronic periodontitis Randomized sampling, double-blind Blinded groups: participants, outcome measurer

Participants/Inclusion and exclusion criteria

Selection criteria: 1.Age at least 18 years 2.Chronic periodontal disease with two wall intrabony defects 3.Similar plaque index(under 15%) 4.The ability to maintain proper oral hygiene; exclusion criteria: 1.Pregnancy 2. Coagulation problems 3.Usage of drugs with interaction with platelet 4.Usage of drugs with interaction with wound healing 5.Any systemic or topical disease which contra-indicated to periodontal treatment 6.Allergy to surgical materials 7.Infective disease (Hepatitis, AIDS, Tuberculosis)

Intervention groups

1.Debridement alone 2.Debridement with applying metformin gel 1% 3. Debridement with applying PRGF 4.Debridement with applying PRGF & metformin gel 1%

Main outcome variables

Vertical clinical attachment level Gingival index Vertical probing depth Radiologic outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100427003813N6**

Registration date: **2018-05-10, 1397/02/20**

Registration timing: **retrospective**

Last update: **2018-05-10, 1397/02/20**

Update count: **0**

Registration date

2018-05-10, 1397/02/20

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

Email address

n.jenabian@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-20, 1396/01/31

Expected recruitment end date

2017-10-01, 1396/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and radiographic evaluation of applying Plasma rich growth factor(PRGF) with Metformin gel 1% in

treating periodontal two-walls intrabony defects

Public title
evaluation of applying Plasma rich growth factor(PRGF) with Metformin gel 1% in treating periodontal intrabony defects

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
At least 18 years old Chronic periodontal diseases with with two wall intabony defects Similar plaque index(under 15%) Ability to maintaing oral hygiene Signing of consenting form
Exclusion criteria:
Pregnancy Existing of coagulation problems use of drugs which interact with platellet use of drugs which interact with wound healing Allergy to surgical materials Infective disease(Hepatitis, AIDS, Tuberculosis) Any topical or systemic disease which containdicated to periodontal treatment

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple

Blinding (investigator's opinion)
Double blinded

Blinding description
patients do not aware of treatment group which they included outcome measurer is different from whom that cures patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committeeof babol university of medical science

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2017-07-29, 1396/05/07

Ethics committee reference number

MUBABOL.REC.1396.49

Health conditions studied

1

Description of health condition studied

Chronic periodontitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

vertical clinical attachment level

Timepoint

at the begining of study and immediately before surgery, 3 and 6 months after sergury

Method of measurement

with perodontal probe

2

Description

gingival index

Timepoint

at the beginning of study, immediately before sugery

Method of measurement

absevational (sillness & Loe)

3

Description

VPD(vertical probing depth)

Timepoint

at the beginning of study, immediately before sugery

Method of measurement

with perodontal probe

4

Description

radiologic outcomes

Timepoint

at the beginning of study and 6 months after study

Method of measurement

parallel technic by means of digital sensor size 2(Soredex.Helsinki-finland)by Rinndentsply film holder

Secondary outcomes

empty

Intervention groups

1

Description

interventional group:open flap debridement with metformin gel 1%

Category

Treatment - Surgery

2

Description

Intervention group 2: open flap debridement with plasma-rich growth factor

Category

Treatment - Surgery

3

Description

Intervention group 3: Open flap debridement with metformin gel 1% and plasma-rich growth factor

Category

Treatment - Surgery

4

Description

Control group: Open flap debridement

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontology departmet of Babol dental faculty

Full name of responsible person

shabnam khalifehzadeh

Street address

Ganjafrooz Ave.

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4717647745

Phone

+98 11 3220 7918

Email

shabnam.kh63ii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

niloofar jenabian

Street address

Ganjafrooz Ave.

City

babol

Province

Mazandaran

Postal code

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Phone

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Email

n.jenabian@mubabol.ac.ir

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

نیلوفر جنابیان

Position

associated professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Postal code

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Phone

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Email

n.jenabian@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

niloofar jenabian

Position

associated professor

Latest degree

Specialist

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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

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

shabnam khalifehzadeh

Position

Resident

Latest degree

Medical doctor