

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the Clinical, histologic and histomorphometric of Ceno Bone ® with and without plasma rich growth factor in dental socket

Protocol summary

Study aim

Clinical, histologic and histomorphometric determine and comparison of Ceno Bone ® with and without plasma rich growth factor in dental socket

Design

Clinical trials with a control group, with parallel groups,

Settings and conduct

The study will be conducted on patients referring to the periodontics department of Babol Dental School, which has a molar un-restorable tooth in the mandible. Sampling was done randomly and for each treatment group, 10 samples and a total of 20 samples were considered. Participants and outcome measurer of this study are blind (double-blind).

Participants/Inclusion and exclusion criteria

Dental Infection, Patients with gingivitis or active untreated periodontitis, Patients with ankylosis of teeth, bone with dehiscence, Diseases that affect tissue repair.

Intervention groups

1.Ridge preservation with applying PRGF, 2.Ridge preservation alone

Main outcome variables

Clinical parameters include vertical changes in dental apicoronal socket, degree of inflammation, trabecular thickness, bone-biomaterial contact, presence or absence of connective tissue in the reconstructed area, percentage of remnant particles, percentage of new bone formation, Number of blood vessels, bone vitality and foreign body reaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100427003813N10**

Registration date: **2019-03-28, 1398/01/08**

Registration timing: **retrospective**

Last update: **2019-03-28, 1398/01/08**

Update count: **0**

Registration date

2019-03-28, 1398/01/08

Registrant information

Name

Niloofer 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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Clinical, histologic and histomorphometric of Ceno Bone ® with and without plasma rich growth factor in dental socket

Public title

Comparison of the Clinical, histologic and histomorphometric of Ceno Bone ® with and without plasma rich growth factor in dental socket

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with non-restoring molar in the lower jaw with indications out volunteer for performing implant have good health availability for follow-up Signature of consent form

Exclusion criteria:

Patients who are not able to perform surgery smoker
Pregnancy Dental Infection Patients with gingivitis or active untreated periodontitis Patients with ankylosis of teeth teeth with dehiscence Diseases that affect tissue repair Patients with certain systemic problems

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups by the coin throwing method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of which treatment group they are. The 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 Committee of Babol Univercity of Medical Science

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.236

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Vertical changes in dental apicoronal socket

Timepoint

before surgery,5 months after surgery

Method of measurement

stent

2

Description

degree of inflammation

Timepoint

5 months after surgery

Method of measurement

histology

3

Description

trabecular thickness

Timepoint

5 months after surgery

Method of measurement

histology

4

Description

bone-biomaterial contact

Timepoint

5 months after surgery

Method of measurement

histology

5

Description

Presence or absence of connective tissue in the reconstructed area

Timepoint

5 months after surgery

Method of measurement

histology

6

Description

percentage of remnant particles

Timepoint

5 months after surgery

Method of measurement

histology

7

Description

percentage of new bone formation

Timepoint

5 months after surgery

Method of measurement

histology

8

Description

Number of blood vessels

Timepoint

5 months after surgery

Method of measurement

histology

9

Description

Bone Vitality

Timepoint

5 months after surgery

Method of measurement

histology

10

Description

foreign body reaction

Timepoint

5 months after surgery

Method of measurement

histology

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Treatment - Surgery

2

Description

Control group: Open flap debridement

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontology Department of Babol Dental Faculty

Full name of responsible person

Farshad Keshavarzi

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Ganjafrooz Ave.

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+98 11 7918 3220

Email

Farshad.Keshavarzi@Gmail.Com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

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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

Email

n.jenabian@mubabol.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Niloofar Jenabian

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Farshad Keshavarzi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

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