Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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
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 Departmet of Babol Dental Faculty
Full name of responsible person
Farshad Keshavarzi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
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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
Associated professer
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