Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

A histologic, histomorphometric and radiographic comparison between two complex of Cenobone/ Cenomembrane and Bio Oss/ Bio Gide in lateral ridge augmentation: a preliminary study.

Protocol summary

Summary

Title: A histologic, histomorphometric and radiographic comparison between two complex of Cenobone/ Cenomembrane and Bio Oss/ Bio Gide in lateral ridge augmentation: a preliminary study. Objectives: The aim of this study is to compare Cenobone/ Cenomembrane and Bio Oss/ Bio Gide in lateral alveolar bone augmentation. Design: This single blind randomized clinical trial is conducted on eight sites which require lateral bone augmentation. Setting and conduct: Samples are selected from subjects seeking implant replacement within the age range of 30 to 50 years and require bone augmentation who present department of periodontology and implant, Faculty of dentistry, Babol University of Medical sciences. The minimum required sample size is evaluated to be 8 for conducting semi experimental clinical trial. Major Inclusion and Exclusion criteria: Samples with alveolar bone width of 2 to 4 mm at distance of 3 mm from the crest are included in the study. Patients with certain systemic conditions which affect healing process, patients with poor compliance, sufferers from active periodontal diseases and subjects who don't want to participate in the study are excluded. Intervention: Patients matching is performed with regard to gender, age, general health, and smoking state of subjects. Patients are assigned to either of two experimental groups. Surgical process is conducted using either of Cenobone/ Cenomembrane and Bio Oss/ Bio Gide in each group. Main outcome measures: six months later at reentry surgery, core biopsies are taken and trabecular thickness, percentage of osseous formation, extent of inflammation, foreign body reaction, vitality, biomaterial/bone contact, and number of blood vessels are evaluated by means of histologic and histomorphometric observations. The radiographic width of alveolar ridge at initial and reentry surgeries is measured using CBCT.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031621494N1**
Registration date: **2015-07-17, 1394/04/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-17, 1394/04/26

Registrant information

Name
Seyed Mohammad Ali Tabatabaei
Name of organization / entity
Babol University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences, Vice chancellor for research and technology

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A histologic, histomorphometric and radiographic comparison between two complex of Cenobone/ Cenomembrane and Bio Oss/ Bio Gide in lateral ridge augmentation: a preliminary study.

Public title
A histologic, histomorphometric and radiographic comparison between two complex of Cenobone/ Cenomembrane and Bio Oss/ Bio Gide in lateral ridge augmentation: a preliminary study.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Subjects within the age range of 30 to 50 years, and with sufficient alveolar bone height who have alveolar ridge width of 2 to 4 mm in the area at a distance of 3 mm from the ridge crest are included in the study. Exclusion criteria: Patients with certain systemic conditions which affect healing process are excluded from the survey, including: Uncontrolled diabetes; immune disorders; alcohol addiction; drug abuse; current smoking; pregnancy; immune suppressor or anticoagulant drugs consumption. Additionally, patients with poor compliance; sufferers from active periodontal diseases which complicate oral hygiene; and subjects who don't want to participate in the study are excluded.

Age
From **30 years** old to **50 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size:

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Ethics committee, Babol University of Medical Sciences, Ganj Afrooz St., Babol.

City
Babol

Postal code
47176- 47745

Approval date
2015-02-07, 1393/11/18

Ethics committee reference number
5121

Health conditions studied

1

Description of health condition studied
Lateral alveolar ridge augmentation

ICD-10 code
k08.2

ICD-10 code description
Atrophy of edentulous ridge

Primary outcomes

1

Description
Lateral ridge augmentation

Timepoint
Six months following grafting

Method of measurement
Radiographic, histologic, and histomorphometric measures

Secondary outcomes

1

Description
Trabecular thickness

Timepoint
Six months following grafting

Method of measurement
Histomorphometric evaluation six months following grafting

2

Description
Number of blood vessels

Timepoint
Six months following grafting

Method of measurement
Evaluation in microscopic fields, six months following grafting

3

Description

Extent of inflammation

Timepoint

Six months following grafting

Method of measurement

Evaluation in microscopic fields, six months following grafting

4

Description

Foreign body reaction

Timepoint

Six months following grafting

Method of measurement

Evaluation in microscopic fields, six months following grafting

5

Description

Bone vitality

Timepoint

Six months following grafting

Method of measurement

Evaluation in microscopic fields, six months following grafting

6

Description

Biomaterial/bone contact

Timepoint

Six months following grafting

Method of measurement

Evaluation in microscopic fields, six months following grafting

7

Description

Biomaterial/bone radiographic density

Timepoint

Six months following grafting

Method of measurement

CBCT examination, six months following grafting

8

Description

Percentage of biomaterial remnants

Timepoint

Six months following grafting

Method of measurement

Histomorphometric evaluation six months following grafting

Intervention groups

1

Description

Intervention group: Cenobone/ Cenomembrane. In this group, Cenobone granules with size of 150 to 1000 microns (Mineralized Cortico Cancellous powder) which have been immersed in normal saline for 30 minutes, are placed in the defected area of bone in such a manner that provide sufficient bone thickness for implant placement in buccal and lingual sides of the ridge. Consequently, absorbable Cenomembrane with thickness of 0.2 to 0.6 microns which originates from allogenic pericardium, is placed over the graft materials. Both bone powder and absorbable membrane are products of Hamanandsaz Baft Kish, Iran.

Category

Treatment - Surgery

2

Description

Intervention group:Bio Oss/ Bio Gide. In this group, Bio Oss granules with size of 500 to 1000 microns which have been immersed in normal saline for 30 minutes, are placed in the defected area of bone in such a manner that provide sufficient bone thickness for implant placement in buccal and lingual sides of the ridge. Consequently, absorbable Bio Gide membrane with standard thickness which originates from pig collagen, is placed over the graft materials. Both bone powder and absorbable membrane are products of Geistlich Biomaterials (Bio Oss, Geistlich Pharma AG, Wolhusen, Switzerland).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of periodontology, Faculty of Dentistry, Babol University of Medical Sciences

Full name of responsible person

Dr Seyed Mohammad Ali Tabatabaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Babol University of Medical Sciences

Full name of responsible person

Dr Ali Akbar Moghadamnia

Street address

Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Ganj Afrooz St., Babol

City

Babol

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology of Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Seyed Mohammad Ali Tabatabaei

Position

Postgraduate student of periodontics

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty