Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical, Histologic and histomorphometric evaluation of Bone Strip Allograft with resorb able membrane in horizontal alveolar ridge augmentation

Protocol summary

Summary

Background & Aim: CenoBone is an allograft-derivated bone bio-implant with different advantages including simple handling and lack of infectious and immune responses. Furthermore, resorption and edentoulus alveolar ridge atrophy is associated with implant treatments requiring alveolar ridge augmentations. CenoBone biomaterial can be effective to induce bone formation or repair bone lesions having positive results in the augmentation of edentoulus ridge for dental implants. The present study will measure clinical, histologic and histomorphometric indices of Bone Strip Allograft with absorbable membrane in the reconstruction horizontal alveolar ridge. Materials & Methods: After local anesthesia, a crestal incision will be made using bistury blade No: 15.0 in the edentoulus ridge of patients following two vertical incisions in the ends of horizontal incision. Full-thickness flap will be raised up to access ridge buccal bone while all soft tissues will be removed. Ridge buccolingual thickness will be measured and validated by 3D bone caliper on the 2, 4 and 10mm distances from the bone crest clinically. Bone strip will be fixed on the bone by 2 screws and hollow strip areas will be filled with demineralized cortical cancellous powder. Cenomembrane membrane will be placed on the graft material. Flap will be placed on the membrane and will be sutured. Five months later and prior to Re-entry; new calculations of ridge buccolingual width on the soft tissue will be made. The specimens will be sent for histologic and histomorphometric assessment. Biopsies will be imaged and the bone formed areas will be assessed regarding percent of bone formations.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202251760N16**
Registration date: **2012-04-28, 1391/02/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-28, 1391/02/09

Registrant information

Name
Nargess Gholizadeh Pasha
Name of organization / entity
Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical, Histologic and histomorphometric evaluation of Bone Strip Allograft with resorb able membrane in horizontal alveolar ridge augmentation

Public title
Clinical, Histologic and histomorphometric evaluation of Bone Strip Allograft with resorb able membrane in horizontal alveolar ridge augmentation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age between 20 to 60 years old; Requiring augmentation and implant restorations; Adequate bone height; Inadequate buccolingual thickness and width (ridge thickness having widths less than 5mm with minimum 2mm measured clinically on the soft tissue). Exclusion criteria: involvement of systemic conditions like uncontrolled diabetes, drug addiction, pregnancy, uncooperative patients and active untreated periodontal disease.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Babol University of Medical Sciences, Gangafroz Avenue

City
Babol

Postal code

Approval date
2012-02-07, 1390/11/18

Ethics committee reference number
5720

Health conditions studied

1

Description of health condition studied
horizontal alveolar ridge augmentation

ICD-10 code
K08.2

ICD-10 code description
Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description
horizontal alveolar ridge augmentation

Timepoint
5 months after putting the bones

Method of measurement
Laboratory

Secondary outcomes

1

Description
The inflammation

Timepoint
5 months after putting the bones

Method of measurement
Laboratory

2

Description
Presence or absence of foreign body reaction

Timepoint
5 months after putting the bones

Method of measurement
Laboratory

3

Description
Properties of bone-biomaterial contact

Timepoint
5 months after putting the bones

Method of measurement
Laboratory

4

Description
Thickness of bone trabeculae

Timepoint

5 months after putting the bones

Method of measurement

Laboratory

5

Description

Bone Vitality

Timepoint

5 months after putting the bones

Method of measurement

Laboratory

Intervention groups

1

Description

Usage of CenoBone; an allograft-derivated bone bio-implant that has many treatment advantages. (Manufacturer: Kish replicating tissue)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Babol

Full name of responsible person

Dr. Amir Kiakojori

Street address

Dental School, Babol University of Medical Sciences, Ganjafruz Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr. Ali Bijani

Street address

Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Gangafroz Avenue

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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

Vice Chancellor for Research and Technology, 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

Dental School, Babol

Full name of responsible person

Dr. Amir Kiakojori

Position

Post graduate student of periodontology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Other areas of specialty/work
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Web page address

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