Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The histological and histomorphometrical evaluation of two grafting materials: cenobone & ITB-MBA in open Sinus Lift Surgery

Protocol summary

Summary

This research is a clinical trial on 6 patients referred to periodontics and dental implant Units of Babol Dentistry College. These patients required dental implants in the posterior maxilla area. The inclusion criteria were patients with general health for whom the implant installation in the posterior maxilla was necessary and had 5mm or less alveolar height. . After a local anesthetia, the horizontal and two vertical incisions were made. After pushing the flap, Window was prepared on the side wall of sinus; and then after placing graft material on sinus bone, the Window surface was covered by a pericardial collagen membrane and stitched.after Six months, implant surgery was performed. On the surgery day, Core biopsy was done after preparing the flap using a Trephine with 3mm diameter and a height of at least 4-5 mm in a space which is supposed to be Implant hole. After demarcation, samples were sent to the pathological laboratory in order to determine the crestal and apical areas. According to the Histomorphometry observations, the thickness of bone trabeculae was determined which had 3 degrees as below: Grade I: more than 60 microns Grade II: between 21 to 60 microns Grade III: between 1 to 20 microns. At any stage, pathologist was not aware of the content of biopsy.To evaluate the residual bone height, panoramic radiography and CBCT were done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081114323N1**
Registration date: **2013-09-30, 1392/07/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-30, 1392/07/08

Registrant information

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2012-09-23, 1391/07/02

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The histological and histomorphometrical evaluation of two grafting materials: cenobone & ITB-MBA in open Sinus Lift Surgery

Public title

The histological and histomorphometrical evaluation of two grafting materials: cenobone & ITB-MBA in open Sinus Lift Surgery

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria:patients required dental implants in the posterior maxilla area;bone height between the floor of the sinus and crestal bone was 5mm or less. Exclusion criteria were: Uncontrollable Systemic diseases such as diabetes; Acute sinusitis; Chemotherapy during the 12 months before surgery; Radiotherapy more than 5000 rad on the neck and face; Psychological problem
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **6**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciencese
Street address
Ganj Afrooz Ave, Babol University of Medical Sciences, Babol, Iran
City
Babol
Postal code
Approval date
2012-09-22, 1391/07/01
Ethics committee reference number
2823

Health conditions studied

1

Description of health condition studied
Biomaterial of Implant surgery
ICD-10 code
K05.6
ICD-10 code description
Periodontal disease, unspecified

Primary outcomes

1

Description
Bone inflammation
Timepoint
Begin of the studuy, 6th month
Method of measurement
Histologic assessment

Secondary outcomes

empty

Intervention groups

1

Description
Cenobone biomaterial
Category
Treatment - Surgery

2

Description
ITB-MBA biomaterial
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol University of Medical Sciences,Periodontics and implant department
Full name of responsible person
Hamid reza safipoor
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Ganj Afrooz Ave, Babol University of Medical Sciences, Babol, Iran
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Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Manager of Research Office,Amrollah Mostafazadeh
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Ganj Afrooz Ave, Babol University of Medical Sciences, Babol, Iran
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Babol

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

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

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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