

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 anesthesia, 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

Name

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Name of organization / entity

Babol University of Medical Sciences

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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 Sciences

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

Street address

Ganj Afrooz Ave, Babol University of Medical Sciences, Babol, Iran

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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

Street address

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

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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