

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Trepine 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

Hamidreza Safipoor

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1326 9728

Email address

hr.safipor@mubabol.ac.ir

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

City

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

Street address

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

City

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

Babol University of Medical Sciences

Full name of responsible person

Hamireza safipoor

Position

Assistant

Other areas of specialty/work

Street address

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

City

Babol

Postal code

Phone

+98 11 1219 9592

Fax

Email

HR.Safipor@mubabol.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Hamidreza safipor

Position

Assistant

Other areas of specialty/work

Street address

Babol University of Medical Sciences

City

Babol

Postal code

Phone

+98 11 1219 9592

Fax

Email

HR.Safipor@mubabol.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Hamidreza safipoor

Position

Assistant

Other areas of specialty/work

Street address

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

City

Babol

Postal code

Phone

00

Fax

Email

HR.safipor@mubabol.ac.ir

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