Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of bone formation in bilateral sinus lift with and without graft

Protocol summary

Study aim

Comparison of bone formation in bilateral sinus lift with and without graft

Design

The study contains 10 patient whom referring to the oral and maxillofacial surgery ward , Babol University medical Science , which have complete or partial edentulous in posterior maxilla and they need bilateral open sinus lift augmentation. Patients will divide in two groups ;case and control. In control group open sinus lift is going to be done with bone material substitution (1cc) and in case group open sinus lift is going to be done alone without any bone substitute.Then Implants will insert . CBCT is taken before surgery and will take 1and 6 months after implants insertion and biopsy will take 6 months after implant insertion. CBCTs will assess with a dental radiologist and biopsies will assess with a dental pathologist for configuration of new bone formation.

Settings and conduct

10 Patients whom need for bilateral open sinus lift refering to the Oral and Maxillofacial Surgery Ward , Babol university of medical science,will devided in 2 groups; case and control Control group: patient who needs open sinus lift on one side with graft augmentation Case group: the same patient in control group who need open sinus lift on the other side without graft augmentation The study is a non randomized double blind one which the patients and the pathologist don't know anything about the side of the graft. We don't make radiologist informed either but due to the opacity of the graft he will understand the graft side himself.

Participants/Inclusion and exclusion criteria

Patients who need bilateral open sinus lift with implant insertion Patients should be medically healthy and without any systemic or metabolic disease Accept the prosthetic treatment plan Accept to sign the consent

Intervention groups

Case groups are patients who need maxillary open sinus lift - without graft Control groups are the same patients whom need maxillary open sinus lift on the other side - with bone graft

Main outcome variables

evaluation of surgical time ; evaluation of cost ; evaluation of complications due to grafting as infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171015036780N4**
Registration date: **2018-03-11, 1396/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-11, 1396/12/20**
Update count: **0**

Registration date

2018-03-11, 1396/12/20

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11321995926

Email address

z.malekpour@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of bone formation in bilateral sinus lift with and without graft

Public title

Comparison of bone formation in bilateral sinus lift with and without graft

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not medically compromised Bilateral complete or partial edentulous in maxilla Bilateral open sinus lift Bone height in alveolar crestal ridge in sinus lift area must be at least 4 mm

Exclusion criteria:

History of having systemic or local disease such as bone metabolic disorder Do not accept prosthetic treatment plan Do not sign the consent

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

biopsy will take from both side by 3mm Trephine Burr and we use bone materials to fill the defect.

Randomization (investigator's opinion)

Not randomized

Randomization description

Individual Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Making pathologist blind by sending unknown specimen to laboratory Two treatment plans was explained for the patient but the patient was not informed about the treatment plan on each side

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

Ganjafrouz St.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2017-12-10, 1396/09/19

Ethics committee reference number

MUBABOL.REC.1396.77

Health conditions studied

1

Description of health condition studied

dental implants

ICD-10 code

ICD-10 code description

2

Description of health condition studied

atrophic ridge of maxilla

ICD-10 code

ICD-10 code description

3

Description of health condition studied

New bone formation in sinus lift procedure

ICD-10 code

ICD-10 code description

4

Description of health condition studied

open sinus lift

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quantity and quality of new bone formation

Timepoint

1 and 6 months after implant insertion

Method of measurement

CBCT and microscopic analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In intervention group open sinus lift is going to be done alone without any bone material
Category
Treatment - Surgery

2

Description
Control group: In control group sinus lift is going to be done with bone material substitution (1cc, xenograft) as a usual procedure in sinus lift
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol University of Medical Science,School of dentistry
Full name of responsible person
Zahra Malekpour Ghorbani
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Sponsors / Funding sources

1

Sponsor
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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
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Amir Zahedpasha
Position
Resident of Maxillofacial Surgery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data allowed to be shared
When the data will become available and for how long
Since 2018
To whom data/document is available
all researchers
Under which criteria data/document could be used
all
From where data/document is obtainable
Email address
What processes are involved for a request to access data/document
After making contact with general responsible person
Comments