

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 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 referring to the Oral and Maxillofacial Surgery Ward , Babol university of medical science,will divided 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

Street address

Babol University of Medical Science,School of dentistry

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Phone

+98 11 3219 9592

Email

zahedpasha_amir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Ganjafruz street

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Mazandaran

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+98 11 3219 4718

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info.research@mubabol.ac.ir

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

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Zahra Malekpour Ghorbani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial surgery

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Web page address**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**Person responsible for updating data****Contact****Name of organization / entity**

Babol university of medical science,dentistry faculty

Full name of responsible person

Amir Zahedpasha

Position

Resident of maxillofacial surgry

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Ganjafruz street

City

Babol

Province

Mazandaran

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