

# 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 be 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

##### City

Babol

##### Province

Mazandaran

##### Postal code

۴۷۱۷۶-۴۷۷۴۵

##### 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

##### City

Babol

##### Province

Mazandaran

#### Postal code

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#### Phone

+98 11 3219 4718

#### Email

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

##### Street address

Ganjafruz street

##### City

Babol

##### Province

Mazandaran

##### Postal code

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##### Phone

+98 11321995926

##### Fax

+98 11 3219 0181

##### Email

zahedpasha\_amir@yahoo.com

##### 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

**Street address**

Ganjafrouz St.

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**Email**

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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

**Postal code**