Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of using collagen foam biomaterial for bone formation in the treatment of open lifting sinus in CBCT images

Protocol summary

Study aim
Determining the effect of using collagen foam biomaterial for bone formation in the treatment of sinus lifting by CBCT of patients referred to Islamic Azad University,Tehran Dental Branch in the 1400

Design
A clinical trial with control group,with parallel group,with blinding, with non-random for 12 patients.

Settings and conduct
The study site is the Department of Surgery, School of Dentistry, Islamic Azad University of Tehran; No blinding was performed in this study.

Participants/Inclusion and exclusion criteria
En Inclusion criteria: with maxillary sinus floor bone less than 3 mm at the implant site Exclusion criteria: no systemic/infectious disease; smoking; Uncontrolled or poorly controlled diabetes; Use of immunosuppressive drugs; Bisphosphonate drugs; History of head and neck radiotherapy; Active maxillary sinus obstruction; Chronic steroid treatment

Intervention groups
Intervention group: Using collagen foam biomaterial as a bonding agent in the treatment of open sinus lifting
Control group:Use of mineralized allograft biomaterial as a graft in the treatment of open sinus lifting

Main outcome variables
Determining the amount of ossification done using CBCT

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210223050469N4**
Registration date: **2021-12-04, 1400/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-04, 1400/09/13**
Update count: **0**

Registration date
2021-12-04, 1400/09/13

Registrant information

Name
Vahid Mesgarzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8878 0179

Email address
vahid_mesgar@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-27, 1400/09/06

Expected recruitment end date
2021-12-07, 1400/09/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of using collagen foam biomaterial for bone formation in the treatment of open lifting sinus in CBCT images

Public title
Evaluation of the effect of using collagen foam biomaterial for bone formation in the treatment of open lifting sinus in CBCT images

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmation of maxillary sinus expansion through panoramic radiography and the need for sinus lifting treatment Patients in the age range of 25 to 65 years
Exclusion criteria:
Presence of systemic /infectious disease Smoking Alcohol consumption Uncontrolled or poorly controlled diabetes Bruxism Taking immunosuppressive drugs Taking bisphosphonate drugs History of head and neck radiotherapy Active maxillary sinus disease Chronic steroid treatment

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **12**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The participant and the outcome evaluator and data analyst do not know the material used. In this way, only the respected surgeon who performs the surgery knows the material used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Azad University of Medical Sciences

Street address
No.9, 9th Neystan, Pasdaran St

City
Tehran

Province
Tehran

Postal code
1946853314

Approval date
2020-08-05, 1399/05/15

Ethics committee reference number
IR.IAU.DENTAL.REC.1399.165

Health conditions studied

1

Description of health condition studied
Evaluation of the effect of using collagen foam in ossification in open sinus lifting operation in comparison with allograft

ICD-10 code
K08.26

ICD-10 code description
Severe atrophy of the maxilla

Primary outcomes

1

Description
Quantity of sinus floor bone

Timepoint
6 months later

Method of measurement
Radiographic measurements by CBCT

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before surgery, CBCT is taken of the desired area and with the software the vertical height of the bone is measured in the specified sections the open sinus lift is then performed using a collagen foam graft made by Etticon company.6 months later, CBCT is performed again and the vertical bone height is measured again in the same sections.

Category
Treatment - Surgery

2

Description
Control group: Before surgery, CBCT is taken of the desired area and with the software the vertical height of the bone is measured in the specified sections the open sinus lift is then performed using a mineralized allograft bonding material made by Kish company .6 months later, CBCT is performed again and the vertical bone height is measured again in the same sections.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University, Tehran Dental Branch

Full name of responsible person
Vahid Mesgarzadeh

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No.9, 9th Neystan, Pasdaran St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Islamic Azad University, Tehran Dental Branch

Full name of responsible person
Arash Azizi

Street address
No.9, 9th Neystan, Pasdaran St

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Drarashazizi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for Research, Islamic Azad University, Tehran Dental Branch

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University

Full name of responsible person
Zahra Saeedi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Dentistry

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Full name of responsible person
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Position
Associate Professor

Latest degree
Specialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available