

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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

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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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

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No.9, 9th Neystan, Pasdaran St

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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

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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Vahid Mesgarzadeh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Zahra Saeedi

Position

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Other areas of specialty/work

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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