

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Histomorphometric examination of sinus floor bone due to the use of foam Collagen compared to mineralized allografts for bone formation in Open sinus lifting without implant placement

Protocol summary

Study aim

Histomorphometric determination of sinus floor bone due to the use of collagen foam biomaterial in comparison with mineralized allograft for bone formation in the treatment of sinus lifting in patients referred to the School of Dentistry of Islamic Azad University of Tehran in 2021

Design

A non-randomized clinical trial with control group, with parallel groups, without blinding, on 20 patients.

Settings and conduct

The study site is the Department of Surgery, School of Dentistry, Islamic Azad University of Tehran; blinding was performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: with maxillary sinus floor bone less than 5 mm at the implant site. Non-inclusion criteria: 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 without implant placement. Control group: Use of mineralized allograft biomaterial as a graft in the treatment of open sinus lifting without implant placement

Main outcome variables

Percentage of ossification by immature and lamellar bones; Angiogenesis; The degree of inflammation and reaction of a foreign body; Percentage of material remaining

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210223050469N3**

Registration date: **2021-11-29, 1400/09/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-29, 1400/09/08**

Update count: **0**

Registration date

2021-11-29, 1400/09/08

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

Histomorphometric examination of sinus floor bone due to the use of foam Collagen compared to mineralized allografts for bone formation in Open sinus lifting without implant placement

Public title

Using foam Collagen bone formation in Open sinus lifting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Has a maxillary sinus floor bone less than 5 mm at the implant site

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
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The participant and statistical analyst does not know which material will be used in each patient

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran Azad University of Medical Sciences

Street address

No.9, 9th Neystan, Pasdaran street

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.284

Health conditions studied

1

Description of health condition studied

maxillary sinus floor pneumatization

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of ossification by immature, lamellar and necrotic bones

Timepoint

Four months later

Method of measurement

Histomofometric measurement of sinus floor bone with ys100 light microscope made in Japan

2

Description

Angiogenesis

Timepoint

Four months later

Method of measurement

Histomofometric measurement of sinus floor bone with ys100 light microscope made in Japan

3

Description

Extent of inflammation and foreign body reaction

Timepoint

Four months later

Method of measurement

Histomofometric measurement of sinus floor bone with ys100 light microscope made in Japan

4

Description

Percentage of material remaining

Timepoint

Four months later

Method of measurement

Histomofometric measurement of sinus floor bone with ys100 light microscope made in Japan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All surgeries are performed in two stages and in the first stage, include open sinus lift is performed using collagen foam bonding material made by Etticon company without implant placement. Then 6 months later, the second stage of surgery, which includes bone sampling with trephine in the bone drill site with implant placement

Category

Treatment - Surgery

2

Description

Control group: All surgeries are performed in two stages and in the first stage, include open sinus lift is performed using mineralized allograft bonding material made by Kish company without implant placement. Then 6 months later, the second stage of surgery, which includes bone sampling with trephine in the bone drill site with implant placement

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 street

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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

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Email

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

Erfan Babaie

Position

Student

Latest degree

A Level or less

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

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Student

Latest degree

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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