Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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No.9, 9th Neystan, Pasdaran street

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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
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

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Name of organization / entity
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Position
Associate professor

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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