Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the use of collagen membranes on the osteotomy window in the open sinus lift approach.

Protocol summary

Study aim

Evluating the effect of using collagen membrane over the osteotomy window on newly formed bone and connective tissue in comparison with not using collagen membrane in lateral sinus lift surgery.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized.

Settings and conduct

30 patients who required maxillary lateral sinus lift and referred to Mashhad Dental School, were evaluated and they were selected for this study.the patients were randomly allocated to control group(membrane) or test group(no membrane).after 6 months, they underwent the second surgery for implant placement. During implant placement, a bone biopsy was removed from the area where the implant was to be inserted and they were sent to the histological laboratory for histological evaluation. After evaluating the quality of histologic slices, newly formed bone and the connective tissue was examined with Image J software, the study was a double-blind study with a blind pathologist analyzing and blind pathologist.

Participants/Inclusion and exclusion criteria

Inclusion criteria:residual bone height 3 to 5 mm, good oral hygiene. Non inclusion criteria:head and neck radiotherapy, uncontrolled diabetes, pregnancy, pathologic lesion or sinus disease, uncontrolled periodontal disease, chemotherapy in the last 12 months before surgery.

Intervention groups

In control group, the bone window was covered with collagen membrane. In intervention group, the bone window wasnt covered with collagen membrane.

Main outcome variables

Measured variables include the amount of newly formed bone and connective tissue.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200125046247N1**
Registration date: **2020-02-15, 1398/11/26**
Registration timing: **retrospective**

Last update: **2020-02-15, 1398/11/26**
Update count: **0**

Registration date

2020-02-15, 1398/11/26

Registrant information

Name

negin jabbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3602 7437

Email address

negin.jb73@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2018-11-24, 1397/09/03

Actual recruitment end date

2019-06-19, 1398/03/29

Trial completion date

2019-06-19, 1398/03/29

Scientific title

Evaluation the use of collagen membranes on the osteotomy window in the open sinus lift approach.

Public title
Evaluation of the use of collagen membranes in comparison with non-use of membranes in sinus floor surgery.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The remaining bone height is 3 to 5 mm. Good oral hygiene.
Exclusion criteria:
Radiotherapy in the head and neck area. Uncontrolled diabetes. Pregnancy. Pathological lesion or sinus disease. Uncontrolled periodontal disease. History of chemotherapy in the last 12 months before surgery.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, randomization is based on random number table. Randomization type: Simple randomization.This method uses simple randomization models such as tap or line, use of random numbers table or computer randomization methods, and each client for example with throws coin, tap and line,put it in the intervention or control group or It is very simple to implement.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double blind study. Statistical analyst and pathologist evaluator were blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad Dental School Ethics Committee
Street address
Faculty of Dentistry,opposite mellat park,vakilabad blv,mashhad.
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۷۷۹۴۸۹۵۹
Approval date
2018-12-19, 1397/09/28
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1397.099

Health conditions studied

1

Description of health condition studied
Study on Maxillary Sinus Lift Surgery.
ICD-10 code
XXI
ICD-10 code description
Factors influencing health status and contact with health services

Primary outcomes

1

Description
The amount of newly formed bone in patients undergoing sinus lift surgery.
Timepoint
Measurement of newly formed bone is performed 6 months after sinus lift surgery and at implant placement time.
Method of measurement
The amount of newly formed bone in each slide was calculated by the image j software. It gives a number that specifies the surface area of each slide. Finally, the number obtained for each patient that represents the amount of newly formed bone is entered into the Statistical Package for Social Sciences(spss)software.

2

Description
The amount of connective tissue in patients undergoing sinus lift surgery.
Timepoint
Measurement of connective tissue is performed 6 months after sinus lift surgery and at implant placement time.
Method of measurement
The amount of connective tissue in each slide was calculated by image j software. It gives us a number that specifies the surface area of each slide. Finally, the numbers obtained for each patient indicating the amount of connective tissue are entered into the Statistical Package for Social Sciences(spss) software.

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" No collagen membrane use over the bone window in open sinus lift surgery. at first the crestal incision was made in the maxillary posterior tooth and lateral sinus wall and two mesial and distal liberator incisions were made for better access, and then the mucopriosteal flap was raised as full-thickness for lateral sinus wall exposure from the bone. Then the bone window was created according to the dimensions of the area. After exposure of the Schneiderin membrane, using sinus membrane brushes, the sinus membrane was separated from the bone and the bone window was directed upward. Then, coarse-grained allografts of size 1000–2000.(Mineralized and Demineralized Blend) was Compressed in Place and Without covering the bone window by the membrane, the mucoperiosteal flap was placed over the area and finally sutured with a 3-0 suture.

Category

Other

2

Description

"Control group:" Use of absorbed collagen membrane with a diameter of 0.2–0.4 mm over the bone window in open sinus lift surgery. at first the crestal incision was made in the maxillary posterior tooth and lateral sinus wall and two mesial and distal liberator incisions were made for better access, and then the mucopriosteal flap was raised as full-thickness for lateral sinus wall exposure from the bone. Then the bone window was created according to the dimensions of the area. After exposure of the Schneiderin membrane, using sinus membrane brushes, the sinus membrane was separated from the bone and the bone window was directed upward. Then, coarse-grained allografts of size 1000–2000.(Mineralized and Demineralized Blend) was Compressed in Place.the bone window was covered with collagen membrane, then the mucoperiosteal flap was placed over the area and finally sutured with a 3-0 suture.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental School

Full name of responsible person

Doctor Mojgan Kazemian

Street address

Faculty of Dentistry,opposite mellat park,vakilabad blv,mashhad.

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Phone

+98 51 3882 9501

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jabbarin921@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Doctor Amin Rahpeyma

Street address

Faculty of Dentistry,opposite Mellat Park,Vakilabad Boulevard,Mashhad.

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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

Mashhad University of Medical Sciences

Proportion provided by this source

30

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

Mashhad University of Medical Sciences

Full name of responsible person

Negin Jabbari

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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Assistant Professor
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Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Position
Student
Latest degree
A Level or less
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