Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison between sinus augmentation with Platelet-Rich Fibrin versus Allogeneic Bone Grafts in stability of one stage implant placement

Protocol summary

Study aim

Comparison of platelet rich fibrin and allogenic bone graft on implant stability

Design

The study will be designed as a double-blind split mouth randomized clinical trial . Samples will be selected from those referred to Qazvin Dental School. 10 patients who need bilateral maxillary sinus agitation will be included in the study after obtaining informed consent

Settings and conduct

Sinus lift in each patient will be performed on both sides laterally using TOLA SINUS KIT. To strengthen the membrane on one side of platelet rich fibrin and the opposite side of collagen membranes Placed. The implants will then be implanted with the same length and diameter on both sides.2 blind Examiners will be selected for stability measurement Stability will be measured by resonance frequency analysis (RFA) method. RFA will be measured immediately after implant placement and 2, 4 and 6 months after implantation and will be compared on both sides.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who need bilateral sinus augmentation.They had to have adequate inter-occlusal and mesiodistal space and sufficient bone width and height . Exclusion criteria: if they were diabetic or had a disease that affects bone metabolism, had a history of previous bone graft or sinus lift, had used immunosuppressive drugs or corticosteroids, or had a history of radiotherapy or chemotherapy.

Intervention groups

Schneiderin membrane lift will be performed on 2 sides to strengthen the membrane on one side of the PRF and on the opposite side of the collagen membranes. The same (diameter 4.5 and length 12) will be installed on both sides. Then the holding abutment will be closed on both sides and followed by suturing.

Main outcome variables

1.Evaluate bone healing time 2.evaluate patient cost if treatment is effective

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191204045602N2**
Registration date: **2020-10-27, 1399/08/06**
Registration timing: **retrospective**

Last update: **2020-10-27, 1399/08/06**
Update count: **0**

Registration date

2020-10-27, 1399/08/06

Registrant information

Name

Aida Karagah

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-08, 1398/03/18

Expected recruitment end date

2020-06-07, 1399/03/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison between sinus augmentation with Platelet-Rich Fibrin versus Allogeneic Bone Grafts in stability of one stage implant placement

Public title
Platelet-Rich Fibrin versus Allogeneic Bone Grafts in stability of one stage implant placement

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who need bilateral sinus augmentation patients with adequate interocclusal and mesiodistal distance for implant placement adequate width for implant placement 5 mm residual bone in each side

Exclusion criteria:
diabetic patients patients with history of bone grafts immunosupressive patients and corticosteroid users patients with history of chemotherapy or radiotherapy

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with sealed envelope and random allocation

Blinding (investigator's opinion)
Double blinded

Blinding description
The double-blind study is designed so that the examiners and statisticians are blind to the two study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
qazvin,blvd bahonar

City
qazvin

Province
Qazvin

Postal code
3419915315

Approval date
2019-04-23, 1398/02/03

Ethics committee reference number
ir.qums.rec.1397.352

Health conditions studied

1

Description of health condition studied
Implant stability measurement

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
stability

Timepoint
Immediately after surgery and 2, 4 and 6 months later

Method of measurement
Stability: With ostell device, the degree of stability (ISQ) is measured based on resonance frequency analysis.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Patients receive 2 grams of amoxicillin prophylactically one hour before surgery. After injection of Local anesthesia , a crystal incision is placed with an anterior releasing incision on both sides of the maxilla. The complete mucopestal flap is removed. Lateral should be created with complete safety and as much as possible without perforation of Schneiderin membranes. Then Schneiderin membrane lift will be performed on 2 sides.On the PRF side is the PRF plug. Then the implants with the same length and diameter (diameter 4.5 and length 12) from BIOTECH brand (kontact biotech dental implant, France with standard protocol according to the manufacturer's guideline with a speed of 800 rpm and a crack of 20 N will be installed on both sides. After surgery, the patient will be advised to use a cold compress at the surgical site and the antibiotic Ko Amoxiclav 375 mg in 20 pieces and gelofen analgesic and chlorhexidine mouthwash 0.12 % Will be prescribed for one week.

Category

Treatment - Surgery

2

Description
Control group:All patients receive 2 grams of amoxicillin prophylactically one hour before surgery. After injection of Local anesthesia, a crystal incision is made with an anterior releasing incision on both sides of the maxilla. The complete mucopestal flap is removed. The sinus lift in each patient is performed laterally on both sides using the TOLA SINUS KIT until the window. Lateral with complete safety and as much as possible without perforation of Schneiderin membranes, then Schneiderin membrane lift will be performed on 2 sides to strengthen the membrane on the opposite side of CENO BONE collagen membranes with a thickness of 0.2-0.6 mm with dimensions of 20 ˟ 20 mm .FDBA bone powder is placed with a particle size of 500-1000 µm, then the implants with the same length and diameter (diameter 4.5 and length 12) will be installed according to the standard protocol according to the manufacturer's guideline with a speed of 800 rpm and a crack of 20 N on both sides. The abutment will be closed on both sides, followed by a suture. After surgery, the patient will be advised to use a cold compress at the surgical site and will be prescribed the antibiotic Co Amoxiclav 375 mg in 20 pieces and gelofen analgesic and 0.12% chlorhexidine mouthwash for one week.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
qazvin university of medical science
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
qazvin university if medical science

Proportion provided by this source
100

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
Qazvin University of Medical Sciences
Full name of responsible person
aida karagah
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Ability to share the main outcome
When the data will become available and for how long
Since 2022
To whom data/document is available
All people related to university centers
Under which criteria data/document could be used
All people related to university centers
From where data/document is obtainable
qazvin dental school maxillofacial department
What processes are involved for a request to access data/document
Must email the researcher to send the data as a file
aida_karagah@yahoo.com
Comments