Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

comparison of the amount of bone structure by the GBR double-layer technique at the same time as placing the implant in the cosmetic area using FDBA and DFDBA

Protocol summary

Study aim

Comparing the amount of bone formation in the bone defect of the aesthetic area by using the change in the layering order of two types of FDBA and DFDBA allografts in the two-layer GBR method

Design

A prospective, non-randomized clinical trial without a control group with parallel groups that was not blinded, phase two, was conducted on 80 selected eligible patients who were divided into two intervention groups of 40 people.

Settings and conduct

Clinically and in a private clinic, a parallel implant has been performed with Double GBR.

Participants/Inclusion and exclusion criteria

80 samples of this study were selected from among patients between the ages of 30 and 60, all with ASA=1; In this way, the tooth in the cosmetic area (in front of the maxilla or mandible) was extracted in the past and the patient came after soft tissue healing; For this purpose, in 80 patients who referred for this purpose, CBCT imaging of the ridge will be performed and the bone condition of the patients will be checked, and a narrow ridge value of about 3 to 4 mm will be considered as an entry criterion. Also, in this evaluation, the brittle exposed area will be seen in the coronal 2/3 on the buccal side after drilling the implant.

Intervention groups

Two intervention groups in which two-lobe GBR was performed with different layering order: Layering order in the first group: FDBA > absorbable collagen membrane > DFDBA > intact periosteum Layering order in the second group: DFDBA > absorbable collagen membrane > FDBA > intact periosteum

Main outcome variables

percentage of bone formation by calculating the area filled in the created cavity; Changes in the amount of bone as a percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230708058713N1**
Registration date: **2023-09-05, 1402/06/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-05, 1402/06/14**
Update count: **0**

Registration date

2023-09-05, 1402/06/14

Registrant information

Name
Raofe Asghari
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2280 2041
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asghari.raha@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
comparison of the amount of bone structure by the GBR double-layer technique at the same time as placing the implant in the cosmetic area using FDBA and DFDBA

Public title
The effect of bone grafting method and the material on bone formation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients have ASA = 1 They have extracted their teeth in front of the maxilla and referred after soft tissue healing. Patients have a narrow ridge of 3 to 4 mm in the aesthetic zone. The primary stability of used implants is above 35. The age of the patients is 30 to 60 years.

Exclusion criteria:
The patient does not have ideal systemic conditions (ASA should not be 1) The patient is over 60 years old.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Islamic Azad University- Dental Branch Tehran - Iran

Street address
Ghods town, simaye iran street ,The central headquarters of the Ministry of Health and Medical Education

City
Tehran

Province
Tehran

Postal code
1467664961

Approval date
2023-06-12, 1402/03/22

Ethics committee reference number
IR.IAU.DENTAL.REC.1402.031

Health conditions studied

1

Description of health condition studied
3 to 4 mm narrow ridge with a 4-wall defect in the buccal two-thirds of the cosmetic area

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
percentage of bone formation; Consistency of results

Timepoint
6 months follow up

Method of measurement
The area filled in the cavity created in the bone using the comparison of two CBCTs at the beginning of the operation and 6 months follow-up

Secondary outcomes

empty

Intervention groups

1

Description
This study has two intervention groups as follows: the samples will be randomly divided into two groups of 40. In the first group, the implant intervention is performed at the same time as the two-layer technique GBR; Antibiotic prophylaxis is given before the procedure; Lidocaine infiltration anesthesia is used and the full thickness mucoperiosteal flap is performed without damaging the periosteum. The incision is made at the apex of the ridge while maintaining a sufficient amount of gingival attachment. Next, in the first group for GBR, 0.3 cc allograft FDBA with 500-1000 nm particles of CenoBone brand is placed in the first layer on the implant, and in the second layer, Ceno Membrane absorbable collagen membrane with a thickness of 0.6 1 mm; In the third layer, 0.3 cc DFDBA allograft with 500-1000 nm particles from Ceno Bone brand is placed, and finally intact periosteum is placed as the fourth layer.

Category
Treatment - Surgery

2

Description
Intervention group:In the second group, all steps are the same as the first group, with the difference that in the first layer, Ceno Bone brand DFDBA with particle size of 500 to 1000 nm is placed in the amount of 0.3 cc, and in the third layer, Ceno Bone brand FDBA with The size of the particles of 500 to 1000 nm is placed in the amount of 0.3 cc. Immediately after the treatment, CBCT is taken, and then the patient is called to close the Helling abutment six months after the treatment, and the amount of bone formation is measured in two groups.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
The private clinic of Dr. Behnaz Pourian

Full name of responsible person
Raofe Asghari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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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
Tehran University of Medical Sciences

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Raofe Asghari

Position
Dentistry Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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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
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
Yes - There is 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
Title and more details about the data/document
Only information about the main outcome
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Relevant academic and scientific institutions
Under which criteria data/document could be used
It can be used to improve clinical skills and increase productivity of oral surgeries
From where data/document is obtainable
Azad Islamic School of Dentistry, address: Pasdaran, 9th Nistan street, contact number: 22564571 and postal code: 19585.175
What processes are involved for a request to access data/document
The request will be made to Azad Islamic Medical Sciences Faculty and reviewed by the Research Council as soon as possible.
Comments