Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of bone powder size on horizontal ridge augmentation by periosteal pocket method

Protocol summary

Study aim
Assessment of graft particle size effect in horizontal ridge augmentation with periosteal pocket flap.

Design
Parallel two-arm group randomized clinical trial with postoperative care and blind outcome evaluation. Excel software rand function was used for randomization.

Settings and conduct
In one group, large DFDBA bone particles and in the other group, small DFDBA bone particles are used for lateral ridge grafting. In both groups, the same surgical procedure using the periosteal pocket flap technique will be used. CBCT is prepared from patients before and 24 weeks after surgery and the amount of horizontal augmentation obtained between the two groups is calculated and compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients referred to the implant ward of Mashhad Dental School, Patients with insufficient bone volume for implant placement, Patients at least 20 years old. Exclusion criteria: People who are not willing to continue cooperation, Patients who are absent from examinations and intend to place implants outside the faculty.

Intervention groups
Twenty patients with one or more extracted tooth areas and severe horizontal collapse of the alveolar ridge who are candidates for horizontal ridge augmentation are randomly divided into two groups of 10 patients. In one group, large DFDBA bone particles are used and in the other group, small DFDBA bone particles are used for lateral ridge grafting. In both groups, the same surgical procedure using the periosteal pocket flap technique will be used for horizontal ridge reconstruction. CBCT is prepared from patients before and 24 weeks after surgery and the amount of horizontal augmentation obtained between the two groups is calculated and compared. Also, the density of the formed bone is recorded and stored in radiography using Hansfield unit determination software.

Main outcome variables
The rate of bone formation.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210706051801N1**
Registration date: **2021-07-08, 1400/04/17**
Registration timing: **prospective**

Last update: **2021-07-08, 1400/04/17**
Update count: **0**

Registration date
2021-07-08, 1400/04/17

Registrant information

Name
Hamidreza Arab

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3882 9501

Email address
arabhr@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-21, 1400/04/30

Expected recruitment end date
2021-11-21, 1400/08/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of bone powder size on horizontal ridge augmentation by periosteal pocket method

Public title

The effect of bone powder size on horizontal augmentation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referred to the implant ward of Mashhad Dental School Patients with insufficient bone volume for implant placement Patients at least 20 years old

Exclusion criteria:

Patients who are not willing to continue cooperation Patients who are absent from examinations and intend to place implants outside the faculty

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be simple and unit of randomization will be individual. Randomization will be done using www.randomization.com and using random numbers in sealed envelopes. Based on the random number in the envelope and its evenness and individuality, the patient will belong to the test and control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

According to the study design, it is not possible to blind the researcher and the clinical caregiver. Study participants are not aware of the size of bone particles and patients' information is not provided to the outcome assessor and data analyzer.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Deputy of Research and Technology, Ghoreshi Building, next to Hoveyzeh Cinema, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-01-13, 1399/10/24

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1399.131

Health conditions studied

1

Description of health condition studied

One or more areas of the tooth are extracted and severe horizontal collapse of the alveolar ridge.

ICD-10 code

K08.2

ICD-10 code description

Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description

The rate of bone formation.

Timepoint

CBCT was prepared from patients before and 24 weeks after surgery and the amount of horizontal agitation obtained between the two groups was calculated and compared.

Method of measurement

The bone density is recorded and stored on radiography using Hansfield unit determination software.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In one group, a small bone particle is used

Category

Treatment - Surgery

2

Description
Intervention group: In one group, a large bone particle is used and then the bone density is checked by cbct.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Dental School
Full name of responsible person
Hamidreza Arab
Street address
Mashhad Dental school, Beginning Vakil Abad Blvd,
City
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arabhr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamidreza Arab
Street address
Deputy of Research and Technology, Ghoreshi Building, next to Hoveyzeh Cinema, University Street.
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arabhr@mums.ac.ir
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
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
Mashhad University of Medical Sciences
Full name of responsible person
Hamidreza Arab
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Deputy of Research and Technology, Ghoreshi Building, next to Hoveyzeh Cinema, University Street.
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available