# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jul 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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Razavi Khorasan
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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
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Deputy of Research and Technology, Ghoreshi Building, next to Hoveyzeh Cinema, University Street.
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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**
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 scientific inquiries

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
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**Position**
Professor
**Latest degree**
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## Person responsible for updating data

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**Position**
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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