Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Radiographic evaluation of crestal bone resorption with and without graft material in the maxillary fresh socket implantation

Protocol summary

Study aim

Radiographic evaluation of crestal bone resorption with 2 types of graft material (Ceno bone and Cera bone) and without graft material in immediate placement of the implant in the central area to the second maxillary premolar

Design

Randomized, controlled clinical trial with 2 parallel group desgn of 45 implant sites. For randomization (coin toss) will be divided into three groups (n=15) based on the type of graft material.

Settings and conduct

Clinical trial will be performed on patients referred to the periodontology department of the School of Dentistry of Babol University of Medical Sciences. The procedure will be performed according to the standard systems designed for Dio implants (Korea).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years old; need for tooth extraction; oral health; proper bone quality; sufficient bone height; the presence of sufficient residual alveolar bone; presence of at least 3 mm of keratinized tissue. Exclusion criteria: smoking; uncontrolled diabetes; poor oral hygiene; pregnant women; need for bone augmentation; receiving corticosteroids; consumption of bisphosphates; untreated periodontal disease; existence of bone defects; malocclusion; unacceptable occlusion; coagulation problems; use of alcohol; abscesses and fistules

Intervention groups

In the control group no grafting material is used in the gap between the fixture and the bone. In the second group xenograft material cerabone (Cerabone, Botiss, Germany) is used in the gap between the fixture and the bone. In the third group allograft material under the brand name cenobone (Hamanand saze baft kish, iran) is used in the gap between the fixture and the bone.

Main outcome variables

Crestal bone resorption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220521054954N1**
Registration date: **2022-07-03, 1401/04/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-03, 1401/04/12**
Update count: **0**

Registration date

2022-07-03, 1401/04/12

Registrant information

Name

Sahar Cheperli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radiographic evaluation of crestal bone resorption with and without graft material in the maxillary fresh socket implantation

Public title
Evaluation of crestal bone resorption in the maxillary fresh socket implantation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years old Need for tooth extraction in the central to second maxillary premolars for traumatic, endodontic or prosthetic reasons oral health (plaque index below 20%) The bone quality in the implant areas in the range of type ll and lll bone density Existence of appropriate bone height in the interradicular area after tooth extraction and proper bone width for implant Placement with a minimum length of 10 mm and a diameter of at least 3.5 mm The sufficient residual alveolar bone to achieve the primary stability of the implant Presence of at least 3 mm of keratinized tissue
Exclusion criteria:
smoking uncontrolled diabetes poor oral hygiene pegnant women need for bone augmentation long-term use of NSAIDs oral or intravenous treatment of bisphosphonates receiving corticosteroids and conditions affecting bone metabolism untreated periodontal disease existence of bone defects malocclusion unacceptable occlusion caused by teeth overgrowth or teeth tilting toward edentulous area severe parafunctional habits coagulation problems use of alcohol abscesses and fistules and lesions that have caused perforation of the buccal and palatal bone
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
N/A
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
Ethics Committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafrooz st.
City
Babol
Province
Mazandaran
Postal code
47148-95498
Approval date
2022-04-24, 1401/02/04
Ethics committee reference number
IR.MUBABOL.REC.1401.033

Health conditions studied

1

Description of health condition studied
Radiographic evaluation of crestal bone resorption in areas with non-maintenance teeth and immediate implant placement
ICD-10 code
M27.6
ICD-10 code description
Endosseous dental implant failure

Primary outcomes

1

Description
Crestal bone resorption
Timepoint
One week after surgery, one month, three months and six months later
Method of measurement
Parallel periapical radiography under standard conditions

Secondary outcomes

empty

Intervention groups

1

Description
Control group: No graft material is used.
Category
N/A

2

Description

Intervention group: Allograft material Ceno bone (Hamanandsaze baft kish, iran)

Category

N/A

3

Description

Intervention group: Xenograft material cera bone (Cerabone, Botiss, Germany)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol University of Medical Sciences, Periodontology department

Full name of responsible person

Nilufar Jenabian

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Babol University of Medical Sciences, Ganjafrooz st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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research@mubabol.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Nilufar Jenabian

Position

Professor

Latest degree

Specialist

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
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
Not applicable
Title and more details about the data/document
Some of the data include preoperative and postoperative measurements
When the data will become available and for how long
The access period starts one year after the results are published
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Approved by the project manager
From where data/document is obtainable
Resident Sahar.cheperlii1991@gmailo.com
What processes are involved for a request to access data/document
After approval by the project manager
Comments