

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the amount of buccal bone plate regeneration using CBCT following immediate implant placement in dental sockets with buccal wall dehiscence by two surgical techniques: open flap and flapless along with GBR

Protocol summary

Study aim

Determining the amount of buccal bone plate reconstruction following immediate implant placement with buccal wall dehiscence with two surgical techniques, open flap and flapless along with GBR by CBCT

Design

The clinical trial has two parallel groups, single blind and a sample size of 24 patients. Randomization is done using the random number generation option of the kitset.ir site

Settings and conduct

Patients applying for immediate implant placement with buccal wall dehiscence referring to Babol Dental Faculty are randomly subjected to open flap and flapless surgery. The height and thickness of the buccal bone wall before surgery and 6 months later were measured by CBCT and the amount of reconstruction. The bone will be evaluated in each group. First group: method without flap, supra crestal fibers are cut before tooth extraction with a 15C surgical blade. After implant implantation, a collagen membrane is prepared according to the size of the pocket in the shape of an ice cream cone to reconstruct the plate, and a bone allograft is also used. Second group: open flap in this group, a crestal and two vertical incisions are made and the flap is raised in full thickness. the type of implant and the type of bone grafting will be the same as the first group.

Participants/Inclusion and exclusion criteria

The main entry conditions include people over 18 years of age with maxillary anterior teeth that have been affected by fractures or endodontic lesions that have led to dehiscence or the loss of the buccal bone plate. The conditions of non-entry include the presence of periodontal disease or gingivitis.

Intervention groups

The study has two groups with two different surgical

techniques. In one group, the surgical technique is flapless, and in the other group, the surgical technique is open flap.

Main outcome variables

Buccal bone height; Buccal bone thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230117057150N1**

Registration date: **2023-01-24, 1401/11/04**

Registration timing: **prospective**

Last update: **2023-01-24, 1401/11/04**

Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

Sima Sangchouli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the amount of buccal bone plate regeneration using CBCT following immediate implant placement in dental sockets with buccal wall dehiscence by two surgical techniques: open flap and flapless along with GBR

Public title

the effect of flapless surgery on bone regeneration following immediate implant placement : the effect of open flap surgery on bone regeneration following immediate implant placement

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with hopeless anterior teeth of the maxilla with buccal wall dehiscence

Exclusion criteria:

The presence of periodontal disease in hopeless anterior teeth of the maxilla People with medical and psychiatric problems for whom surgery is contraindicated Smokers and alcoholism pregnant women People with bruxism or other parafunctional dental habits

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly divided into two groups: randomization will be done using the random number generation option of the kitset.ir website, so that the first half will be in the flapless group and the second half will be in the open flap group.

Blinding (investigator's opinion)

Single blinded

Blinding description

CBCT images are blindly analyzed by a radiologist in order to evaluate the regeneration of dental socket buccal bone plate 6 months after the intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Babol University of Medical Sciences

Street address

ganj afrouz street

City

Babol

Province

Mazandaran

Postal code

4774547176

Approval date

2023-01-09, 1401/10/19

Ethics committee reference number

IR.MUBABOL.REC.1401.157

Health conditions studied**1****Description of health condition studied**

Dehiscence of buccal wall of dental socket

ICD-10 code

K08.9

ICD-10 code description

Disorders of teeth and supporting structures, unspecified

Primary outcomes**1****Description**

Buccal bone height: dependent variable, quantitative continuous; The method of measurement is from the most coronal part of the remaining bone crest to the floor of the nasal cavity or maxillary sinus.

Timepoint

CBCT time before surgery and 6 months after surgery.

Method of measurement

Buccal bone height: The method of measurement in CBCT images is from the most coronal part of the remaining bone crest to the floor of the nasal cavity or maxillary sinus in millimeters.

2**Description**

Buccal bone thickness: dependent variable, quantitative continuous; The method of measurement is from the apical millimeter of the crest of the buccal bone.

Timepoint

CBCT time before surgery and 6 months after surgery.

Method of measurement

The thickness of the buccal bone: the method of measurement is from the apical millimeter of the crest of the buccal bone in millimeters.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: flapless surgery technique, The surgical protocol will require atraumatic extraction of the tooth without a flap. Dental debridement and clinical examination will be performed to assess the lack of labial plate and ensure the presence of sufficient interproximal bone. Osteotomy is performed with a palatal inclination to place the implant. In this study, tapered implant (DIO) will be used. After planting the implant, a pocket remains relative to the buccal plate. A collagen membrane (cenoderm-kish-iran) is prepared in the shape of an ice cream cone to reconstruct the plate. The membrane is placed inside the remaining buccal bone plate, and the bone graft (FDBA) with a particle size of 500-1000 micrometers, 0.25-0.5 cc (CenoBone-Kish-Iran) is placed in the implant gap and buccal contour. After socket filling with Bone graft, the coronal part of the membrane is folded to cover the socket, and a horizontal mattress suture is placed on the palate to stabilize the membrane. CBCT images using a planmeca device (finland) are prepared before surgery (T0) and 6 months (T1) after recovery in order to evaluate the amount of buccal bone plate regeneration.

Category

Treatment - Surgery

2

Description

Intervention group: open flap surgery technique, In this group, after tooth extraction, first a crestal incision and two vertical incisions are made, and the flap is raised in full thickness until 2 to 3 mm of the buccal bone is exposed. For greater flexibility of the flap and the possibility of closing the surgical site, a periosteal incision is given. The steps of implantation, the type of implant and the type of bone graft will be similar to the first group. CBCT images using a planmeca device (finland) are prepared before surgery (T0) and 6 months (T1) after recovery in order to evaluate the amount of buccal bone plate regeneration.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Dental School

Full name of responsible person

Sima Sangchouli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mahdi Rajabnia

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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

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

Dr. Majid Fereyduni

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)

Undecided - It is not yet known if there will be 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

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

No - There is not 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

The data will be identified and stored by assigning a code

When the data will become available and for how long

After finishing the study and publishing its article

To whom data/document is available

Researchers and academics

Under which criteria data/document could be used

Due to the acquisition of the code of ethics of researchers by the Deputy of Research and Technology of Babol University of Medical Sciences, the documents will be usable

From where data/document is obtainable

Dr. Majid Fereyduni, Babol University of Medical Sciences

What processes are involved for a request to access data/document

Checking the eligibility of the applicant and having the code of ethics will be done by an academic center.

Comments