Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

Phone
+98 11 3219 9592

Email address
sima_sangchouli@yahoo.com

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

Street address
Palestine Ave، Noshirvani Blvd

City
Babol

Province
Mazandaran

Postal code
4717643633

Phone
+98 11 3229 1408

Fax
+98 11 3229 1093

Email
sima_sangchouli@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr. Mahdi Rajabnia

Street address
Nurse Ave, University Square, Murad Beg Town

City
Babol

Province
Mazandaran

Postal code
4717643633

Phone
+98 11 3239 1408

Fax
+98 11 3229 1093

Email
sima_sangchouli@yahoo.com

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
Periodontology and Implantology

Street address
Nurse Ave، University Square، Morad Beg Town

City
Babol

Province
Mazandaran

Postal code
4717643633

Phone
+98 11 3229 1408

Email
golpasha@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr. Majid Fereyduni

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
Periodontology and Implantology

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4717643633

Phone
+98 11 3229 1408

Email
golpasha@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr. Majid Fereyduni

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
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Email
golpasha@yahoo.com

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 Fereduni، 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