Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effects of two incision designs; Double flap and Periosteal releasing, on soft tissue changes following guided bone regeneration, in patients with horizontal ridge defect on posterior mandible

Protocol summary

Study aim

Determining and comparing the effects of Double flap incision(DFI) and Periosteal releasing incision(PRI) on soft tissue changes following guided bone regeneration

Design

Clinical trial with control group, with parallel groups, double-blinded, randomized, on 24 patients. To randomize the samples, the random numbers generation option of the kitset.ir site was used.

Settings and conduct

The study population includes 24 patients referred to the periodontology department of Babol University of Medical Sciences, who have inclusion and exclusion criteria and will be randomly divided into two groups and will go under GBR surgery. The surgical method adopted in group 1 is DFI. In group 2, the gold standard method, PRI, will be used for surgery. Patients are followed up on the third day and 1, 2, 4, 12 and 24 weeks after surgery, and the desired indexes are collected by a blind examiner in prepared data sheets. Due to the fact that the patient and the examiner do not know the surgical technique, the study will be double-blinded.

Participants/Inclusion and exclusion criteria

Patients over 21 years of age with severe horizontal alveolar bone deformity (Seibert Class I) and in need of GBR treatment in the posterior mandibular region without a history of smoking and systemic disease or unexplained allergies are included in the study.

Intervention groups

A GBR will be used before implant placement in both groups. The surgical method adopted in group 1 to reduce tension for flap advancement includes the DFI technique. In group 2, the gold standard method, PRI, will be used for surgery.

Main outcome variables

Persistent discomfort, pain, swelling, bleeding, the amount of recovery of patients at the surgical site, flap advancement, membrane exposure, infection, paraesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100427003813N13**
Registration date: **2023-03-06, 1401/12/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-06, 1401/12/15**
Update count: **0**

Registration date

2023-03-06, 1401/12/15

Registrant information

Name

Niloofar Jenabian

Name of organization / entity

Dental Faculty of University of Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1229 1408

Email address

n.jenabian@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date
2023-08-23, 1402/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of two incision designs; Double flap and Periosteal releasing, on soft tissue changes following guided bone regeneration, in patients with horizontal ridge defect on posterior mandible

Public title
Comparison of the effects of two incision designs; Double flap and Periosteal releasing, on soft tissue changes following guided bone regeneration (GBR)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Has severe horizontal alveolar bone deformity(Seibert Class I) and requires guided bone regeneration treatment in the posterior region of the mandible
Exclusion criteria:
History of smoking History of systemic disease History of unexplained allergies
Age
From **21 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize the samples, the option of generating random numbers on the kitset.ir site was used. For this purpose, random numbers from 1 to 24 was generated as follows, the first half of which case number will be operated by Double flap incision (DFI) method and the second half by Periosteal releasing incision (PRI) method. In the checklist of each patient, only one number is written and the surgical technique used is not specified, so neither the patient nor the examiner knows about the surgical technique used.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participant (patient) and the examiner who performs the examination in the follow-up appointments and records the results in the data sheet, do not know which group the patient is in and which surgical technique was used for the patient, because the type of technique will not be recorded in the patient's data sheet, and patients will only be identified by a number and from the appearance of the surgical site, the type of technique cannot be recognized. so the study is double-blinded. The only person who knows the surgical technique is the surgeon, who is not involved in recording the results.
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
University of medical sciences, Ganj afrooz street, Babol
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2022-11-28, 1401/09/07
Ethics committee reference number
IR.MUBABOL.HRI.REC.1401.184

Health conditions studied

1

Description of health condition studied
Severe horizontal alveolar bone deformity(Seibert Class I)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of flap advancement during surgery
Timepoint
During surgery, before tension freeing the flap with one of techniques and after that
Method of measurement
Measuring the amount of the flap advancement compared to its base during surgery with UNC-15 probe

Secondary outcomes

1

Description
Membrane exposure
Timepoint
3rd day and 1, 2, 4, 12 and 24 weeks after surgery
Method of measurement
Did membrane exposed in the mouth in follow-up stages or not?

2

Description
Infection
Timepoint
3rd day and 1, 2, 4, 12 and 24 weeks after surgery
Method of measurement
Is there pus at the surgical site in the follow-up stages or not?

3

Description
Paraesthesia
Timepoint
3rd day and 1, 2, 4, 12 and 24 weeks after surgery
Method of measurement
Is there sensory disorders related to surgery in the follow-up stages or not?

4

Description
Continuous discomfort
Timepoint
3rd day and 1, 2, 4, 12 and 24 weeks after surgery
Method of measurement
Is there any expression of discomfort in the surgical area by the patient in the follow-up stages or not?

5

Description
Pain
Timepoint
3rd day and 1, 2, 4, 12 and 24 weeks after surgery
Method of measurement
by Visual Analogue Scale

6

Description
Swelling
Timepoint
3rd day and 1, 2, 4, 12 and 24 weeks after surgery
Method of measurement
by Visual Analogue Scale

7

Description
Bleeding
Timepoint
3rd day and 1, 2, 4, 12 and 24 weeks after surgery
Method of measurement
by Visual Analogue Scale

8

Description
Healing of surgery site
Timepoint
3rd day and 1, 2, 4, 12 and 24 weeks after surgery
Method of measurement
by Wound healing index

Intervention groups

1

Description
Intervention group: The surgical method adopted in this group to reduce tension for flap advancement includes partial thickness flap elevation, which leaves the periosteal layer on the edentulous ridge and separates the mucosal layer of the flap. The periosteal layer of the flap stabilizes the reconstruction site using periosteal sutures. A crestal incision will be made with a vertical releasing incision 2 mm from the most distal tooth with a #15 blade. The crestal incision will be extended distal to the flap to avoid traction. Then a partial thickness flap that separates the mucosal flap from the periosteum that covers the alveolar bone, will be made on the buccal side. After sufficient separation between the external (mucosal) and internal (periosteal) flaps, the periosteal flap will be raised from the bone surface. Then a full thickness lingual mucoperiosteal flap is raised. After that, a 1˟2 cm collagen membrane from Kish Tissue Replicator will be used to create a space free of soft tissue. The bone defect will be filled with half a cc of freeze-dried mineralized bone allograft from Kish Tissue Replicator. The periosteal flap will be placed and fixed with 4-0 Vicryl sutures using two horizontal sutures.
Category
Treatment - Surgery

2

Description
Control group: In this group, the gold standard method, periosteal releasing incision, will be used for surgery. In the missing tooth site with horizontal bone defect, an incision will be made using a 15 blade to divide the gingival flap into 2 equal parts. The flap is elevated full thickness on both buccal and lingual sides. Then, to free the flap from tension, a periosteal incision is made with a 15 blade on both buccal and lingual sides. Then, as in Group 1, a collagen membrane will be used to create a soft tissue-free space. The bone defect will be filled with freeze-dried mineralized bone graft. The flap will be fixed with 4-0 vicryl figure C sutures.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Periodontology, Faculty of Dentistry, Babol University of Medical Sciences

Full name of responsible person
Doctor Niloofar Jenabian

Street address
University of medical sciences, Ganj afrooz Street, Babol

City
Babol

Province
Mazandaran

Postal code
4717647745

Phone
+98 11 3219 9592

Email
njenabian@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Doctor Mehdi Rajabnia

Street address
University of Medical Sciences, Ganj afrooz Street, Babol

City
Babol

Province
Mazandaran

Postal code
4717647745

Phone
+98 11 3219 9592

Email
info@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
Niloofar Jenabian

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
University of medical sciences, Ganj afrooz Street, Babol

City
Babol

Province
Mazandaran

Postal code
4717647745

Phone
+98 11 1229 1408

Fax
+98 11 1229 1093

Email
n.jenabian@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Niloofar Jenabian

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
University of medical sciences, Ganj afrooz Street, Babol

City
Babol

Province
Mazandaran

Postal code
4717647745

Phone
+98 11 1229 1408

Fax
+98 11 1229 1093

Email
n.jenabian@mubabol.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Niloofar Jenabian

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
University of medical sciences, Ganj afrooz Street, Babol

City
Babol

Province
Mazandaran

Postal code
4717647745

Phone
+98 11 1229 1408

Fax
+98 11 1229 1093

Email
n.jenabian@mubabol.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
The data will be available to researchers working in academic and scientific institutions or people working in industry

Under which criteria data/document could be used
It is possible to use data or documents for further studies or to choose a more appropriate treatment method for patients

From where data/document is obtainable
To receive documents or data, contact Dr. Niloofar Jenabian at the following email address. njenabian@hotmail.com

What processes are involved for a request to access data/document
Wait for a reply by sending a request email to the above address

Comments