

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

Niloofer 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

AgeFrom **21 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget 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

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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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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Niloofar Jenabian

Position

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Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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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