

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the success rate of dental implants after Alveolar buccal cortex Reconstruction using Palatal bone graft

Protocol summary

Study aim

Determination of the success rate of dental implants after alveolar buccal cortex reconstruction using palatal bone graft

Design

Clinical trial, convenience sampling, preliminary study in 15 patients

Settings and conduct

In 15 patients referred to the oral, maxillofacial surgeon's office who are candidates for implants in maxillary incisors and have buccal defects; After tooth extraction and implant placement, crushed palatal bone graft will be used to reconstruct the buccal wall, and xenogeneic graft and collagen membrane will be used on it for guided bone regeneration (GBR). The success rate of these implants will be evaluated by examining the rate of bone resorption, the rate of failure, the rate of dehiscence and the rate of wound infection in the 6-month follow-up after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Candidate to receive an implant in maxillary incisors 2) Loss of buccal cortex of implant during surgery up to half of the implant 3) Availability of palatal bone for transplantation Exclusion criteria: 1) History of previous surgery in the desired area

Intervention groups

After extracting the teeth and placing the implant, the palatal graft will be harvested using the trephine method. The graft will be placed over the missing buccal area. Xenogenous graft and collagen membrane for GBR will be used on it. Amoxicillin, ibuprofen, chlorhexidine 0.12% mouthwash will be prescribed.

Main outcome variables

The rate of bone resorption Implant failure Envelope depth wound dehiscence wound infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221111056472N1**

Registration date: **2022-12-15, 1401/09/24**

Registration timing: **prospective**

Last update: **2022-12-15, 1401/09/24**

Update count: **0**

Registration date

2022-12-15, 1401/09/24

Registrant information

Name

Parisa Seydabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3334 2127

Email address

parisaseydabadi6@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the success rate of dental implants after Alveolar buccal cortex Reconstruction using Palatal bone graft

Public title

Application of Palatal bone graft in dental implants

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

candidate to receive an implant in the anterior of the maxilla (incisors) Loss of buccal cortex of implant during surgery up to half of the implant Intactness of other bone walls Availability of palatal bone for transplantation Intact soft tissue for implant coverage The patient's health in terms of systemic issues

Exclusion criteria:

Non-cooperation of the patient in terms of compliance with health issues Failure to visit the patient for follow-up Previous surgical history of the desired area

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics Committee of Semnan University of Medical Sciences

Street address

Research and Technology Vice-Chancellor, Central Headquarters of Semnan University of Medical Sciences, Basij Blvd.

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2022-10-25, 1401/08/03

Ethics committee reference number

IR.SEMUMS.REC.1401.180

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

Placement of dental implants in the anterior of the maxilla after reconstruction of the buccal cortex using palatal bone grafting

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The amount of bone loss

Timepoint

Three months and six months after surgery

Method of measurement

Periapical radiograph

2**Description**

Implant success

Timepoint

Three months and six months after surgery

Method of measurement

observation

3**Description**

probing depth of the pocket on the buccal surface of the implant

Timepoint

Three months and six months after surgery

Method of measurement

Michigan-O periodontal probe William's Color Coded Marking

4**Description**

Wound dehiscence

Timepoint

Three months and six months after surgery

Method of measurement

observation

5**Description**

Wound infection

Timepoint

Three months and six months after surgery

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In 15 patients who visited the oral, maxillofacial surgeon's office, after teeth extraction and implant placement with the standard protocol, the palatal bone graft will be harvested using the trephine (crushed bone) method. The graft will be placed over the missing buccal area. Xenogenous bone graft and collagen membrane for guided bone regeneration (GBR) will be used on it. The soft tissue will be returned to the grafted area and fixed in place with a simple suture. For patients, Amoxicillin antibiotic every 8 hours for one week, Ibuprofen pain reliever every 6 hours for 48 hours and Chlorhexidine 0.12% mouthwash twice a day for one week will be prescribed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral, maxillofacial surgeon's office

Full name of responsible person

Mohammad Esmaeilnejad

Street address

2nd floor, Ferdous commercial service complex,
Moalem square, Semnan, Iran

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3514898533

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+98 23 3334 0786

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esmaeelnejad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Majid Mirmohammadkhani

Street address

Research and Technology Vice-Chancellor, Central
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majidmirmohammadkhani@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

1

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

Semnan University of Medical Sciences

Full name of responsible person

Parisa Seydabadi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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meters of Vahdat Boulevard

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Person responsible for scientific inquiries

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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

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

Undecided - It is not yet known if there will be a plan to make this available