Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Crestal Bone Loss in 2 groups with different Seating Torque in the same implant system

Protocol summary

Study aim
Comparison of Crestal Bone Loss in 2 groups with different Seating Torque in the same implant system

Design
This study is designed as a randomized, double-blind clinical trial. Forty-eight eligible patients, who meet the inclusion criteria, will be selected and randomly allocated into two groups. Stratified randomization will be employed, utilizing the web-based calculator available at http://www.graphpad.com/quickcalcs/index.cfm.

Settings and conduct
This study will assess patients at the Mashhad School of Dentistry Implant Department, randomized into two groups: one receiving implant placement at 25–30 N·cm torque, and the other at 55–60 N·cm torque, utilizing a subcrestal technique. Sample size is determined based on comparable studies. Post-implantation, a baseline parallel periapical radiograph will be taken, followed by a second at 4 months to quantify crestal bone loss. Measurements will be double-assessed by two Oral and Maxillofacial Radiologists for reliability.The trial will employ a double-blinded design (patients and the assessors), with all implantations performed by a single operator using the Neodent system. Data will be analyzed via SPSS.23 with a statistical significance threshold of α=0.05.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients referred to the Implant Department of the Faculty of Dentistry, Mashhad. Patients who have sufficient bone volume for implant placement. Consent to participate in the study. Exclusion Criteria: Substance abuse and addiction. Use of medications known to interfere with bone osseointegration. Presence of systemic diseases. Presence of periodontal disease.

Intervention groups
In the control group, the implant will be placed with a torque of 25 to 30 Newton Centimeters. In the other group, the implant will be placed with a torque of 55 to 60 Newton Centimeters.

Main outcome variables
Crestal bone loss (millimeter)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250723066612N1**
Registration date: **2025-11-06, 1404/08/15**
Registration timing: **prospective**

Last update: **2025-11-06, 1404/08/15**
Update count: **0**

Registration date
2025-11-06, 1404/08/15

Registrant information

Name
nafiseh nikzat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 912 963 0764

Email address
nikzatnafiseh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-21, 1404/08/30

Expected recruitment end date
2026-04-20, 1405/01/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Crestal Bone Loss in 2 groups with different Seating Torque in the same implant system

Public title

Comparison of Crestal Bone Loss in 2 groups with different Seating Torque in the same implant system

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referred to the Implant Department of the Faculty of Dentistry, Mashhad Patients who have sufficient bone volume for implant placement Consent to participate in the study

Exclusion criteria:

Consumption of narcotic drugs and addiction Use of drugs affecting bone osteointegration Having systemic diseases Having periodontal disease

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization (Stratified randomization) is performed using the website http://www.graphpad.com/quickcalcs/index.cfm. Central randomization (Central randomization) is performed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blinding is implemented such that both the participants and the researchers—including those involved in selection, data collection, and outcome assessment—are blinded to the group allocation of each individual. In other words, neither the patient nor the research team is aware of the implant’s seating torque value assigned to the participant, ensuring the prevention of any bias or influence on the study outcomes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, School of Dentistry, Mashhad University of Medical Sciences

Street address

Mashhad School of Dentistry, Opposite Mellat Park, Vakil Abad Blvd. Beginning, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2024-10-12, 1403/07/21

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1403.143

Health conditions studied

1

Description of health condition studied

The amount of crestal bone loss around the implant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of crestal bone loss

Timepoint

The level of the crestal bone will be measured immediately following implant placement and subsequently at 4 months post-operation.

Method of measurement

At the specified time points, a parallel periapical radiograph will be obtained, and subsequently, the crestal bone level will be compared.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: In the intervention group, implants will be placed with an insertion torque ranging from 55 to 60 Ncm. All patients in this group will receive Neodent

implants, which will be positioned using a subcrestal, two-stage surgical protocol. Immediately following the surgery, a baseline radiograph will be obtained utilizing the paralleling technique. The second radiograph will be captured four months post-surgery, coinciding with the second-stage procedure for the connection of the healing abutment, and will be taken using the identical paralleling technique.

Category

Treatment - Surgery

2

Description

Intervention Group: In the intervention group, implants will be placed with an insertion torque ranging from 25 to 30 Ncm. All patients in this group will receive Neodent implants, which will be positioned using a subcrestal, two-stage surgical protocol. Immediately following the surgery, a baseline radiograph will be obtained utilizing the paralleling technique. The second radiograph will be captured four months post-surgery, coinciding with the second-stage procedure for the connection of the healing abutment, and will be taken using the identical paralleling technique.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Implant department of Mashhad School of Dentistry

Full name of responsible person

Ershad Aghasizadeh Shoorbaf

Street address

Mashhad School of Dentistry, Opposite Mellat Park, Vakil Abad Blvd. Beginning, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Email

aghaszadehe@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Mashhad University of Medical Sciences

Full name of responsible person

Ershad Aghasizadeh Sharbaf

Street address

Mashhad School of Dentistry, Opposite Mellat Park, Vakil Abad Blvd. Beginning, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Email

aghaszadehe@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Nafiseh Nikzat

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No.33,jahed 1

City

Mashhad

Province

Razavi Khorasan

Postal code

9184313827

Phone

+98 912 963 0764

Fax

Email

nikzatnafiseh@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Nafiseh Nikzat

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

Street address
No.33,jahed 1

City
Mashhad

Province
Razavi Khorasan

Postal code
9184313827

Phone
+98 912 963 0764

Fax

Email
nikzatnafiseh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Nafiseh Nikzat

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

Street address
No.33,jahed 1

City
Mashhad

Province
Razavi Khorasan

Postal code
9184313827

Phone
+98 912 963 0764

Fax

Email
nikzatnafiseh@gmail.com

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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
IPD: Raw data after cleaning included study variables such as demographic information, type of intervention, and outcomes for each individual patient Study protocol: Complete text of study protocol including objectives, study design, randomization and blinding methods, inclusion/exclusion criteria, definitions, and measurement tools. Statistical Analysis Plan: Detailed description of statistical methods, software used, models, and assumptions for tests. Informed Consent Form: Fully signed informed consent forms by participants or template consent form. Clinical Study Report: Comprehensive report including results, discussion, conclusions, patient data summary, and statistical analyses.

When the data will become available and for how long
Participant Data File (IPD): From 6 months after the publication of the main study results for at least 5 years. Study Protocol: Available simultaneously with main study publications and archived permanently. Statistical Analysis Plan: Available after publication of primary results, for at least 5 years. Informed Consent Form: Maintained permanently after data collection is completed and publication is permitted. Clinical Study Report: Available after article publication and retained for at least 5 years.

To whom data/document is available
Participant Data File (IPD): Official research center members, researchers with approved related research proposals, and other researchers upon ethical committee and research team approval. Study Protocol: Open access for all researchers and scientific audiences without restrictions. Statistical Analysis Plan: Researchers involved in further analyses or meta-analyses with approved requests. Informed Consent Form: Only study team members and ethical committees. Clinical Study Report: Relevant researchers, regulatory bodies, scientific users for legitimate purposes.

Under which criteria data/document could be used
Participant Data File (IPD): Strictly for research purposes such as secondary analyses or meta-analyses with protection of participant confidentiality and anonymity. Study Protocol: For study review, educational use, and as a reference for similar studies. Statistical Analysis Plan: For reviewing analytical approaches and use in similar research. Informed Consent Form: Verification of ethical compliance in the study. Clinical Study Report: Reviewing results, use in systematic reviews, research projects.

From where data/document is obtainable
Participant Data File (IPD): Written request to the responsible for the research or the Vice President for Research at Mashhad University of Medical Sciences at

the email address RAMResearch@mums.ac.ir Study Protocol: Download via official research center website or by email request. Statistical Analysis Plan: Written request to data analysis lead at the research center. Informed Consent Form: Internal request with ethical committee review if needed. Clinical Study Report: Written request reviewed and approved by research group.

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

Participant Data File (IPD): Initial evaluation by research team, ethics committee approval, signing a data use agreement, and delivery after confidentiality agreements are in place. Study Protocol: Automatic/manual sending upon email request without special authorization. Statistical Analysis Plan: Review of the request based on purpose, approval, and confidentiality agreement before delivery Informed Consent Form: Formal permission required; not available to external parties to ensure confidentiality. Clinical Study Report: Request assessment and permission under confidentiality agreements.

Comments

Participant Data File (IPD): Commercial use is prohibited unless explicitly approved in agreements. Study Protocol: Provided in PDF format Statistical Analysis Plan: May include explanatory sessions if needed. Informed Consent Form: Personal identifiers are removed or coded for privacy. Clinical Study Report: Delivered electronically in PDF or suitable formats.