Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Marginal Bone Loss Around Crestal and Subcrustal Dental Implants

Protocol summary

Study aim
Comparison of marginal bone resorption around crestal and subcrustal implants

Design
Parallel randomized clinical trial with 2×2 factorial design. Participants are stratified according to crestal soft tissue thickness (≥2 mm or <2 mm) and then randomly allocated to crestal or subcrustal implant group within each stratum.

Settings and conduct
Dental School, Mashhad University of Medical Sciences, Implant Department. The study will be conducted on an outpatient basis. All surgeries will be performed by a specialist surgeon under standardized conditions.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: - Age 20-50 years - Need for placement of at least 2 dental implants in non-adjacent edentulous areas - At least 4 months after tooth extraction with healed alveolar ridge - Sufficient bone volume at implant site (minimum width 7 mm, height 13 mm) - No uncontrolled systemic diseases - Willingness to participate and sign informed consent **Exclusion Criteria:** - Drug abuse or addiction - Poor oral hygiene - Medications affecting osseointegration - Bone defects at the implant site - Active periodontal disease - Unwillingness to continue participation

Intervention groups
This study has four intervention groups based on 2×2 factorial design: - Group 1: Crestal implant + crestal soft tissue thickness ≥ 2 mm - Group 2: Crestal implant + crestal soft tissue thickness < 2 mm - Group 3: Subcrustal implant + crestal soft tissue thickness ≥ 2 mm - Group 4: Subcrustal implant + crestal soft tissue thickness < 2 mm All implants are from the NeoDent system and placed in a one-stage surgery under standardized conditions.

Main outcome variables
Marginal bone loss (MBL) at mesial and distal aspects of the implants, measured using parallel periapical radiographs at baseline (immediately after placement), 3 months, and 6 months after implant placement.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260615069803N1**
Registration date: **2026-06-19, 1405/03/29**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-19, 1405/03/29**
Update count: **0**

Registration date
2026-06-19, 1405/03/29

Registrant information

Name
Amirhossein Hesami Shakib

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 4466 3228

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amir.hesami3228@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-06-18, 1405/03/28

Expected recruitment end date
2026-12-19, 1405/09/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Marginal Bone Loss Around Crestal and Subcrustal Dental Implants

Public title
Evaluation of Marginal Bone Loss Around Crestal and Subcrustal Dental Implants Considering Crestal Soft Tissue Thickness: A Randomized Controlled Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20 and 50 years Good general health Written informed consent Minimum bone width of 7 mm Minimum bone height of 13 mm At least 4 months after tooth extraction

Exclusion criteria:
Systemic diseases Periodontal disease Drug abuse Poor oral hygiene

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

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified Block Randomization

Blinding (investigator's opinion)
Single blinded

Blinding description
This is a single-blind randomized clinical trial. The radiographic evaluator is blinded to the implant placement type and group allocation. The surgeon and patients cannot be blinded due to the nature of the surgical intervention. Statistical analysis will also be performed by a blinded analyst.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
No. 33, North Kosar Ave, Vakil Abad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9178686317

Approval date
2026-03-10, 1404/12/19

Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1404.114

Health conditions studied

1

Description of health condition studied
Marginal bone loss around dental implants (Crestal and Subcrestal implant placement)

ICD-10 code
Z46.3

ICD-10 code description
Encounter for fitting and adjustment of dental prosthetic device

Primary outcomes

1

Description
Marginal bone loss (MBL) at the mesial and distal aspects of dental implants, measured using parallel periapical radiographs

Timepoint
Baseline (immediately after implant placement), 3 months, and 6 months after implant placement.

Method of measurement
Parallel periapical radiographs taken at mesial and distal sides of each implant. The distance from the implant-abutment junction to the first visible bone-to-implant contact will be measured using radiographic analysis software

Secondary outcomes

1

Description
Evaluation of peri-implant soft tissue parameters including Papilla Index, width of keratinized mucosa, and interproximal papilla status, as well as incidence of complications (peri-implantitis, infection, or implant failure)

Timepoint
Baseline (immediately after placement), 3 months, and 6 months after implant placement

Method of measurement
Clinical examination by a periodontist and radiographic

assessment when indicated.

Intervention groups

1

Description
Intervention group: Dental implant placement in crestal (at bone crest level) or subcrestal (2 mm below bone crest) position. All implants are from the Neodent system and placed using a standardized one-stage surgical protocol. The study follows a 2×2 factorial design (implant position × soft tissue thickness).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental School, Mashhad University of Medical Sciences
Full name of responsible person
Motahare Damavandi
Street address
Dental School, Mashhad University of Medical Sciences Beginning of Vakilabad Boulevard, opposite Mellat Park (or Azadi Square area), Mashhad, Iran
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motaharedmv@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Naser Sargolzayi
Street address
Dental School, Mashhad University of Medical Sciences Beginning of Vakilabad Boulevard, opposite Mellat Park (or Azadi Square area), Mashhad, Iran
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RAMResearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Motahare Damavandi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Specialist

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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
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
Not applicable
Title and more details about the data/document
Anonymized Individual Participant Data (IPD) and Study Protocol
When the data will become available and for how long
6 months after publication of the main study results
To whom data/document is available
Qualified scientific researchers who submit a formal request (subject to approval by the ethics committee and principal investigator)
Under which criteria data/document could be used
Only for legitimate scientific research purposes, with strict preservation of participant anonymity. Any secondary publication or use requires written permission from the principal investigator.
From where data/document is obtainable
Principal Investigator (Motahare Damavandi) or the Supervisor (Dr. Hamidreza Arab)
What processes are involved for a request to access data/document
Requests must be submitted in writing along with a research proposal to the principal investigator. The request will be reviewed by the research team and, if approved by the ethics committee, the data will be provided to the applicant.
Comments