Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Using Osseodensification Drills on the Stability of Dental Implants in the Maxilla: A Randomized Split-Mouth Clinical Trial

Protocol summary

Study aim

To evaluate the effect of using osseodensification drills on the stability of dental implants in the maxilla compared with the conventional drilling technique.

Design

This study will be conducted as a randomized double-blind clinical trial with a split-mouth design. Randomization will be performed using the permuted block method.

Settings and conduct

This study will be conducted at the Department of Periodontology, Faculty of Dentistry, Rasht. Twelve eligible patients will be enrolled. For each patient, implant site preparation will be randomly assigned to either osseodensification drilling or conventional drilling on one side of the maxilla, with the contralateral side receiving the alternate technique two weeks later. All implants (DIO, 3.8 × 10 mm, regular platform) will be placed using a standardized surgical protocol. Patients and outcome assessors will be blinded to the drilling technique used on each side.

Participants/Inclusion and exclusion criteria

Eligible participants will be adults (≥18 years) requiring bilateral maxillary premolar implants with at least 6 months of post-extraction healing and D3–D4 bone density. Exclusion criteria includes local infection or pathology, parafunctional habits, anatomical limitations, medications or systemic conditions that could impair bone healing.

Intervention groups

Each patient will serve as their own control. One side of the maxilla received osseodensification drilling (Charisma kit, Pakistan) and the contralateral side conventional drilling (DIO kit, South Korea). Implant placement will be performed two weeks later.

Main outcome variables

Primary outcomes include implant primary stability. Secondary outcomes included changes in peri-implant bone density, marginal bone loss, patient-reported pain and discomfort, implant success rate , and surgical time required for each drilling protocol.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260124068649N1**
Registration date: **2026-01-30, 1404/11/10**
Registration timing: **prospective**

Last update: **2026-01-30, 1404/11/10**
Update count: **0**

Registration date

2026-01-30, 1404/11/10

Registrant information

Name
Sanaz Asadi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-19, 1404/11/30

Expected recruitment end date

2026-03-19, 1404/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Using Osseodensification Drills on the Stability of Dental Implants in the Maxilla: A Randomized Split-Mouth Clinical Trial

Public title
The Effect of Using Osseodensification Drills on the Stability of Dental Implants

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 years or older Indication for placement of two implants in the premolar regions on both sides of the jaw, in edentulous areas at least 6 months after tooth extraction Bone density: D3–D4

Exclusion criteria:
Presence of acute or chronic infection or local pathology at the intended implant placement site Patients with parafunctional habits Limitations to implant placement, such as insufficient vertical bone height Use of medications that interfere with bone healing, such as corticosteroids, hormone therapy, or bisphosphonates History of uncontrolled systemic diseases or conditions that interfere with bone healing, including smoking, diabetes, immunosuppression, fibrous dysplasia, bleeding disorders, hyperparathyroidism, pregnancy, and a history of head and neck radiotherapy or chemotherapy within the past 5 years

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **12**
More than 1 sample in each individual
Number of samples in each individual: **2**
Implant site preparation for two implants in each patient will be performed using either osseodensification drills or conventional drills.

Randomization (investigator's opinion)
Randomized

Randomization description
In this split-mouth randomized clinical trial, treatment type and jaw side are allocated using permuted block randomization with a block size of 4. The random sequence is generated using SAS software (version 9), with A/B indicating treatment type and C/D indicating jaw side. Only the data analyst is aware of the allocation codes. Allocation concealment is ensured using sealed, opaque, numbered envelopes prepared by an independent researcher. After patient enrollment, one envelope is opened to determine the assigned treatment and jaw side. Implant surgery is performed by one researcher, while data collection and outcome assessment are carried out by another researcher blinded to allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
The intervention will be performed bilaterally in the maxilla for each patient, and both drilling techniques (osseodensification and conventional drilling) will be used in every participant. Participants will be blinded to the allocation of the drilling technique to each side. The surgical procedures will be performed by one investigator, while outcome assessment and data collection will be carried out by a second investigator who is blinded to group allocation. Only the data analyst will have access to the treatment codes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Guilan university of medical sciences

Street address
Fouman - Saravan Rd

City
Rasht

Province
Guilan

Postal code
4194173774

Approval date
2026-01-14, 1404/10/24

Ethics committee reference number
IR.GUMS.REC.1404.475

Health conditions studied

1

Description of health condition studied
Maxillary Partial Edentulism requiring Dental Implants

ICD-10 code
K08.4

ICD-10 code description
Partial loss of teeth

Primary outcomes

1

Description
Implant Stability
Timepoint
Immediately, 2, 8, and 12 weeks after implant placement
Method of measurement
Implant stability will be measured using the AnyCheck device (Neo Biotech, South Korea) in direct contact with the healing abutment.

Secondary outcomes

1

Description
Marginal Bone Loss
Timepoint
Three months after implant placement
Method of measurement
Measurement of the distance between the first thread of the implant and the crestal bone on parallel periapical radiographs, recorded in tenths of a millimeter.

2

Description
Patient-reported Pain & Discomfort
Timepoint
Immediately after the surgery and one week after implant placement.
Method of measurement
The level of pain and discomfort experienced by patients will be measured using the Visual Analog Scale (VAS).

3

Description
Initial survival rate
Timepoint
Three months after implant placement
Method of measurement
Evaluating the survival rate of the implants in the follow-up session.

4

Description
Bone density
Timepoint
12 weeks after implant placement
Method of measurement
The bone density of the area around the implant will be classified using CBCT and the Lekholm & Zarb classification into five categories: D1, D2, D3, D4, and D5

Intervention groups

1

Description
Interventions group: In the intervention group, implant site preparation will be performed using the osseodensification technique. For this purpose, the Charisma osseodensification drill kit (manufacturer: Pakistan) will be used.In this technique, the drills are operated in a counter-clockwise rotation with the aim of compacting and preserving the peri-implant bone. Unlike conventional drilling, this method is a non-excavation technique, in which bone is not removed from the osteotomy site.Osteotomy preparation will be carried out according to the manufacturer's instructions. After completion of the osteotomy, Dio dental implants with dimensions of 8.3 × 10 mm (regular type) will be placed using an implant motor at a speed of 30 rpm and an insertion torque of 30 Ncm.
Category
Treatment - Devices

2

Description
control group: In the control group, implant site preparation will be performed using the conventional subtractive drilling technique. A standard DIO drilling kit (manufactured in South Korea) will be used according to the manufacturer's recommended protocol.In this method, the osteotomy is prepared through gradual removal of bone, with sequential use of drills of increasing diameters until the final osteotomy size is achieved.Following site preparation, implants with specifications identical to those used in the intervention group (Dio, 8.3 × 10 mm, regular type) will be placed at a speed of 30 rpm and an insertion torque of 30 Ncm.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Periodontics Department, Facurlty of Dentistry, Guilan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Rasht 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
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Position
Associated Professor
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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