

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Implant Stability and Radiographic Crestal Bone Loss Between HA/coated and RBM Short Dentis Implants in Posterior Maxilla

Protocol summary

Summary

Aim: Comparison of implant stability and radiographic crestal bone loss between HA/coated and RBM short Dentis implants in patients with edentulism in posterior maxilla. Study Design: Interventional; Single Blind; Uni-center; 2-3 trial phase. population: With age limit; no sex limit. Inclusion criteria: Patients with range of 20-65 years old; Plaque index 25% or less before surgery; Presence of 2 edentulous area adjacent or counterpart; At least 9mm crestal bone height to maxillary sinus floor; At least 6mm bone width; Insertion torque between 20-50 Ncm. Exclusion criteria: Patients with any infectious or systemic diseases; smokers; history or presence of periodontitis; Fresh Socket Implantation; Need of supplemental surgery such as ridge splitting and ridge augmentation. b- Intervention: Placement of Dentis HA coated implants. Control: Placement of Dentis RBM implants. Time of intervention: 6 months. Primary or under study outcome measures: Perio test value; Radiographic crestal bone loss.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101611134N1**

Registration date: **2013-01-30, 1391/11/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-30, 1391/11/11

Registrant information

Name

Nasim Farkhani

Name of organization / entity

Islamic Azad Dental School Khorasgan Branch,
(Isfahan)

Country

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2012-11-05, 1391/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Implant Stability and Radiographic Crestal Bone Loss Between HA/coated and RBM Short Dentis Implants in Posterior Maxilla

Public title

Implant Stability and Radiographic Crestal Bone Loss Between HA/coated and RBM Short Dentis Implants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with range of 20-65 years old; Plaque index 25% or less before surgery; Presence of 2 edentulous area adjacent or counterpart; At least 9mm crestal bone height to maxillary sinus floor; At least 6mm bone width; Insertion torque between 20-50 Ncm. Exclusion criteria: Patients with any infectious or

systemic diseases; smokers; history or presence of periodontitis; Fresh Socket Implantation; Need of supplemental surgery such as ridge splitting and ridge augmentation.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Islamic Azad Dental School
Khorasgan Branch, (Isfahan), Iran

Street address

Islamic Azad University Khorasgan (Isfahan) Branch,
University Boulevard, Arghavanieh, Eastern Jay
Street, Isfahan, Iran. Isfahan Isfahan Iran, Islamic
Republic Of

City

Isfahan

Postal code

00983116641410

Approval date

2012-04-28, 1391/02/09

Ethics committee reference number

91020909302

Health conditions studied

1

Description of health condition studied

Partial edentulous in posterior maxillary segments

ICD-10 code

k08.1

ICD-10 code description

Loss of teeth due to accident, extraction or local periodontal disease

Primary outcomes

1

Description

Numerical value of PTV

Timepoint

0, 1, 3 months after surgery and 3 months after loading

Method of measurement

By means of a Periotest device

2

Description

Radiographic crestal bone loss

Timepoint

0, 1, 3 months after surgery and 3 months after loading

Method of measurement

By use of parallel periapical radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Placement of Dentis HA coated implants.

Category

Treatment - Surgery

2

Description

Control: Placement of Dentis RBM implants.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad Dental School Khorasgan Branch,
(Isfahan)

Full name of responsible person

Nasim Farkhani

Street address

Islamic Azad University Khorasgan (Isfahan) Branch,
University Boulevard, Arghavanieh, Eastern Jay
Street.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research of Islamic Azad Dental School Khorasgan Branch, (Isfahan)

Full name of responsible person

Payam Najafi

Street address

Islamic Azad University Khorasgan (Isfahan) Branch, University Boulevard, Arghavanieh, Eastern Jay Street.

City

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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

Vice chancellor for Research of Islamic Azad Dental School Khorasgan Branch, (Isfahan)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad Dental School Khorasgan Branch, (Isfahan)

Full name of responsible person

Nasim Farkhani

Position

Postgraduate student of periodontics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty