Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Position
Postgraduate student of periodontics

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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