Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of marginal bone level around bone-level and tissue-level short implants in posterior maxilla

Protocol summary

Summary

The aim of this study is to compare marginal bone loss around tissue-level and bone-level short dental implants in posterior maxilla. Study is designed as randomized controlled clinical trial. Patients who seek dental implant in posterior area of maxilla, with approximately 6-10 millimeters of bone height in desired area for implant insertion, and sinus augmentation is not indicated for them are included in the study. Patients with active periodontal disease are excluded. After obtaining informed consent from patient, one or more (depending on the treatment plan) short implant/implants are inserted in posterior sextant of maxilla which are chosen as bone-level or tissue-level randomly. A standardized parallel periapical radiograph is then obtained. After healing period, prosthesis is delivered and a standardized periapical radiograph is taken. Six months later another standardized periapical radiograph with the same adjustments is taken. Marginal bone level is compared between radiographs for each implant and the mean of marginal bone loss -as primary outcome- for bone-level group and tissue-level group are compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021025662N2**
Registration date: **2017-06-11, 1396/03/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name
Solmaz Akbari
Name of organization / entity
Dental school, Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 88249184
Email address
soolmaz.akbari@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2018-10-01, 1397/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of marginal bone level around bone-level and tissue-level short implants in posterior maxilla

Public title

Evaluation of marginal bone level around short maxillary implants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Edentulous area of at least one tooth missed in the posterior sextant of maxilla; which is considered to be treated with implant supported fixed prosthesis; available bone height of at least 6 mm and less than 10 mm below the maxillary sinus in the area

planned for implant insertion, as observed in CBCT radiograph; available bone width of at least 6 mm in the area planned for implant insertion as observed in CBCT radiograph; sinus augmentation not planned, because of medical reasons or patient's unwillingness; and patient's willing for cooperation with the study. Exclusion criteria: Active periodontal disease (Probing pocket depth >=4 mm with bleeding on probing); full mouth plaque score >20% at time of implant placement; full mouth bleeding score >20% at time of implant placement; smoking >10 cigarettes/day; systemic disease or conditions which influence bone metabolism; and bruxism or clenching.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **16**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Tehran University of Medical Sciences

Street address
Keshavarz blvd, Ghods ave, Head quarter of Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2017-03-25, 1396/01/05

Ethics committee reference number
IR.TUMS.VCR.REC.1396.1988

Health conditions studied

1

Description of health condition studied
Dental implant

ICD-10 code
Z96.5

ICD-10 code description
K00-K14Presence of tooth-root and mandibular implants

2

Description of health condition studied
Edentuous ridge atrophy

ICD-10 code
K08.2

ICD-10 code description
Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description
Marginal bone level changes

Timepoint
At implant placement, prosthesis delivery and 6 months later

Method of measurement
a standardized radiograph is taken For evaluation of marginal bone level, CBCT viewer software is used for assessing the radiographs. the distance between bone to implant contact and platform of each implant, at mesial and distal of implants were calculated at each intervals.

Secondary outcomes

1

Description
Probing depth

Timepoint
At prosthesis delivery and 6 months later

Method of measurement
O’ Michigan, Williams marking probe

2

Description
Bleeding on probing

Timepoint
At prosthesis delivery and 6 months later

Method of measurement
Bleeding on probing with O’ Michigan, Williams marking, which may happen till 30 seconds later

3

Description
Implant survival rate
Timepoint
At prosthesis delivery and 6 months later
Method of measurement
Percentage of remained implants in oral cavity at the end of study

Intervention groups

1

Description
Intervention group: Patients who meet inclusion criteria, after signing an informed consent enter the study. Surgery for implant placement: Patients rinse their mouth with chlorhexidine 2.2% mouthrinse. Local anesthesia is applied. Then, buccal flap is reflected and before reflecting palatal one, mucosal thickness of palatal tissue in center area of placing implant is measured and recorded. Now, an assistant opens the envelope which determines due to randomization, which type of implant should be inserted for the patient. Implant of Euroteknika brand are to be used in this study; test group will receive Aesthetica tissue-level implants. The length of implant chosen is 6 or 8 millimeters, depending on the available bone. Drilling and placing implant at desired level relative to bone crest is done according to manufacturer's instruction. One week later, after suture removal, a standardized parallel periapical radiograph is obtained from study implants. For this, a digital sensor, mounted on an XCP film holder- which is bound to a piece of putty material for registering the exact position of the sensor and tube relative to the implant- is used. The putty can then be used in two other radiographs to provide identical geometry as the first one. Three months after inserting implants, impression making begins and prosthesis is delivered. Type of prosthesis to be used is cemented porcelain-fused-to- metal crowns. At the time of prosthesis delivery, probing depth and bleeding on probing around implant, and full mouth plaque index are recorded, and a standardized radiograph, as described before, is taken. Six months later, PD, and BoP of the implant, and FMPI are recorded, and a standardized radiograph is taken For evaluation of marginal bone level, CBCT viewer software is used for assessing the radiographs. First, each radiograph is given a code by a blind person out of the study, then one of the investigators make measurements on the image. The measurements to be made are: 1-"Bone level": the distance between the most coronal point of implant-bone contact to the most coronal point of implant platform in either mesial and distal sides. 2- the distance between implant apex and its shoulder, which is used to calibrate other measurements of the graph. Differences in bone level between the radiographs is obtained after calibrating the measures [primary outcome]. Mean marginal bone loss for the test group -tissue level implants- is calculated and compared to the control's.
Category
Treatment - Surgery

2

Description
Control group: Patients who meet inclusion criteria, after signing an informed consent enter the study. Surgery for implant placement: Patients rinse their mouth with chlorhexidine 2.2% mouthrinse. Local anesthesia is applied. Then, buccal flap is reflected and before reflecting palatal one, mucosal thickness of palatal tissue in center area of placing implant is measured and recorded. Now, an assistant opens the envelope which determines due to randomization, which type of implant should be inserted for the patient. Implant of Euroteknika brand are to be used in this study; control group will receive Natea bone-level implants. The length of implant chosen is 6 or 8 millimeters, depending on the available bone. Drilling and placing implant at desired level relative to bone crest is done according to manufacturer's instruction. One week later, after suture removal, a standardized parallel periapical radiograph is obtained from study implants. For this, a digital sensor, mounted on an XCP film holder- which is bound to a piece of putty material for registering the exact position of the sensor and tube relative to the implant- is used. The putty can then be used in two other radiographs to provide identical geometry as the first one. Three months after inserting implants, impression making begins and prosthesis is delivered. Type of prosthesis to be used is cemented porcelain-fused-to- metal crowns. At the time of prosthesis delivery, probing depth and bleeding on probing around implant, and full mouth plaque index are recorded, and a standardized radiograph, as described before, is taken. Six months later, PD, and BoP of the implant, and FMPI are recorded, and a standardized radiograph is taken For evaluation of marginal bone level, CBCT viewer software is used for assessing the radiographs. First, each radiograph is given a code by a blind person out of the study, then one of the investigators make measurements on the image. The measurements to be made are: 1-"Bone level": the distance between the most coronal point of implant-bone contact to the most coronal point of implant platform in either mesial and distal sides. 2- the distance between implant apex and its shoulder, which is used to calibrate other measurements of the graph. Differences in bone level between the radiographs is obtained after calibrating the measures [primary outcome]. Mean marginal bone loss for the control group -bone level implants- is calculated and compared to the test's.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of periodontics, Tehran University of Medical Sciences, School of Dentistry

Full name of responsible person
Mina Taheri
Street address
Tehran university dental school, North Amirabaad, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr Amirreza Rokn
Street address
Tehran university dental school, North Amirabaad, Tehran
City
Tehran
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, Tehran University of Medical Sciences
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
Department of periodontics, Tehran University of Medical Sciences, School of Dentistry
Full name of responsible person
Mina Taheri
Position
Postgraduate student
Other areas of specialty/work
Street address
Tehran university dental school, North Amirabaad, Tehran
City
Tehran
Postal code
Phone
+98 21 8835 1170
Fax
Email
mtaherim@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of periodontics, Tehran University of Medical Sciences, School of Dentistry
Full name of responsible person
Soolmaz Akbari
Position
Assistant professor
Other areas of specialty/work
Street address
Tehran university dental school, North Amirabaad, Tehran
City
Tehran
Postal code
Phone
+98 21 8835 1170
Fax
Email
soolmaz.akbari@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of periodontics, Tehran University of Medical Sciences, School of Dentistry
Full name of responsible person
Mina Taheri
Position
Postgraduate student
Other areas of specialty/work
Street address
Tehran university dental school, North Amirabaad, Tehran
City
Tehran
Postal code
Phone
+98 21 8835 1170
Fax
Email
mtaherim@gmail.com
Web page address

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