

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of bone loss in patients treated with Iranian implant 3A: An uncontrolled clinical trial

Protocol summary

Study aim

Clinical and radiologic evaluation of 3A Iranian implant system

Design

This study is a phase 2 clinical trial study . 76 implants will be studied and patients will be admitted to the study voluntarily and non-randomly from individuals over 18 years of age.

Settings and conduct

This study will be conducted in Implant Research Center Tehran University of Medical Science. 3A implant will be inserted in the proper location and chlorhexidine 0.2% and Gelofen 400 mg will be prescribed for patients. Immediately after surgery and 3 month later(before prosthesis delivery) implant's stability will be assessed by Ostell mentor. Clinical evaluation(including pocket depth, plaque index, bleeding on probing and presence of Pus) will be done in 3,6 and 12 month post surgery. One week after surgery(after suture removal), 3, 6 and 12 months later parallel periapical radiography will be taken. Finally radiography will be evaluated for mesial and distal bone resorption by radiologist.

Participants/Inclusion and exclusion criteria

inclusions criteria: Short 3 unit bridge or single edentulous; 1 mm bone around implant exclusion criteria: 1/need of augmentation around implant; 2/presence pus; 3/ heavy smoker; 4/ uncontrolled diabetes or another diseases;

Intervention groups

3A implant with proper size with 1 millimeter bone around implant will be used.

Main outcome variables

pocket depth; bleeding on probing; plaque index; bone loss; Implant stability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210802052053N2**

Registration date: **2021-11-09, 1400/08/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-09, 1400/08/18**

Update count: **0**

Registration date

2021-11-09, 1400/08/18

Registrant information

Name

Mohadeseh Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8351

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heidarim@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-11-01, 1401/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of bone loss in patients treated with Iranian implant 3A: An uncontrolled clinical trial

Public title

evaluation of dental implant 3A

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Single edentulous or short 3-unit bridge The presence of one millimeter bone around the implant
Exclusion criteria:
 the need of augmentation in implant region presence of pus in implant region heavy smoker uncontrolled diabetes or any systemic diseases bisphosphonate usages active periodontal disease bruxism and clenching pregnancy

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Tehran University of Medical sciences
Street address
 Faculty of Dentistry, North Kargar Ave, Enghelab square
City
 Tehran
Province
 Tehran
Postal code
 ۱۴۳۹۹۵۵۹۹۱
Approval date
 2021-10-09, 1400/07/17
Ethics committee reference number
 IR.TUMS.DENTISTRY.REC.1400.145

Health conditions studied

1

Description of health condition studied
 Single edentulous or three-unit bridge
ICD-10 code
 K08.1
ICD-10 code description
 Complete loss of teeth

Primary outcomes

1

Description
 bone loss
Timepoint
 Immediately, 3,6 and 12 month after surgery
Method of measurement
 periapical radiography

Secondary outcomes

1

Description
 pocket depth
Timepoint
 3,6 and 12 months after surgery
Method of measurement
 periodontal probe

2

Description
 bleeding on probing
Timepoint
 3,6 and 12 months after surgery
Method of measurement
 periodontal probe

3

Description
 plaque index
Timepoint
 3,6 and 12 months after surgery
Method of measurement
 periodontal probe

4

Description
 implant stability
Timepoint
 Immediately, 3 months after surgery (before prosthesis delivery)
Method of measurement
 Implant stability measuring device (Osstell)

Intervention groups

1

Description

Intervention group: Iranian Dental Implant 3A Surgery produced by Dorinkasht mana

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental implant research center

Full name of responsible person

Mohadeseh Heidari

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Dental Research Institute, Tehran university of medical sciences, ghods St, Enghelab Av, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hamidreza Barikani

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohadeseh Heidari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

Specialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Phone**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