

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Evaluation of bone loss in patients treated with Iranian implant Avita who referred to Dental Implant Research Center: An uncontrolled clinical trial

#### Protocol summary

##### Study aim

clinical and radiographic evaluation of dental implant system Avita

##### 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. Avita 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

Inclusion criteria: patient over 18 years; single edentulous or 3 unit bridge; 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

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

##### Main outcome variables

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

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20210802052053N1**

Registration date: **2021-10-18, 1400/07/26**

Registration timing: **prospective**

Last update: **2021-10-18, 1400/07/26**

Update count: **0**

#### Registration date

2021-10-18, 1400/07/26

#### Registrant information

##### Name

Mohadeseh Heidari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8897 8351

##### Email address

heidarim@sina.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-10-22, 1400/07/30

#### Expected recruitment end date

2022-10-22, 1401/07/30

#### 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 Avita who referred to Dental Implant Research Center: An uncontrolled clinical trial

## Public title

evaluation of dental implant Avita

## 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 diseases using bisphosphonate 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

1439955991

#### Approval date

2021-10-09, 1400/07/17

#### Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1400.144

## 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 prosthetics delivery)

#### Method of measurement

Implant stability measuring device (Osstell)

## Intervention groups

1

### Description

Intervention group: Iranian dental implant system Avita

### Category

Treatment - Devices

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Dental implant research center

#### Full name of responsible person

Mohadeseh Heidari

#### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

1981613441

#### Phone

+98 21 8897 8351

#### Email

heidarim@sina.tums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Hamidreza Barikani

#### Street address

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

#### City

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#### Postal code

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#### Phone

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#### Email

hrBarikani@tums.ac.ir

#### 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

#### Street address

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

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohadeh Hiedari

#### Position

Assistant professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ghazal Jabalameli

**Position**

Dentist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

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**Email**

ameli.ghazal@gmail.com

**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