

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

comparing the amount of marginal bone loss between bone-level and tissue-level implants in posterior site of mandible

Protocol summary

Study aim

comparing the amount of marginal bone loss between bone-level and tissue-level implants in posterior site of mandible

Design

we randomly divided patients to two groups, getting different implant types. the implants were made by the same manufacturer and were placed by the same surgeon to avoid technical errors.

Settings and conduct

in this study all of the patients underwent surgery by the same surgeon and had received dental implants at the missing site of mandible. immediately after placement of implant, periapical radiography of the implant provided by parallel technique. also periapical radiographies provided after implant prothesis cementation and after 1-year follow-up. by comparing these radiographies, we measure and evaluate the amount of marginal bone loss

Participants/Inclusion and exclusion criteria

patients with missed teeth at the region of first or second mandibular molars

Intervention groups

we placed bone-level and tissue-level implants in two group of patients to replace missed mandibular molars

Main outcome variables

the implant type with less amount of marginal bone loss will be known as the better choice for replacing mandibular molars

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210516051311N1**

Registration date: **2022-02-25, 1400/12/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-25, 1400/12/06**

Update count: **0**

Registration date

2022-02-25, 1400/12/06

Registrant information

Name

roozbeh azadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7729 8679

Email address

roozbeh.azadi051@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-13, 1400/11/24

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the amount of marginal bone loss between bone-level and tissue-level implants in posterior site of mandible

Public title

comparing the amount of marginal bone loss between bone-level and tissue-level implants in posterior site of mandible

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with missed tooth at the region of first or second mandibular molars

Exclusion criteria:

Patients with systematic disorders
Smoker patients
Patients require bone grafting before implant surgery

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly we use bone-level or tissue-level implants for patients. Patients whom approved for implant placement, divided to two groups using random function of scientific calculator, creating numbers between 0 and 1. if the number is between 0 and 0.5 patient is assigned to bone level group, otherwise tissue level group is chosen.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of biomedical research of dental science of shahid beheshti medical university

Street address

shahid beheshti university of medical science - velenjak

City

تهران

Province

Tehran

Postal code

1985717443

Approval date

2022-02-12, 1400/11/23

Ethics committee reference number

IR.SBMU.DRC.REC.1400.155

Health conditions studied

1

Description of health condition studied

implant

ICD-10 code

M27.61

ICD-10 code description

Osseointegration failure of dental implant

Primary outcomes

1

Description

marginal bone loss

Timepoint

after prothesis cementation, after 1-year follow-up

Method of measurement

on parallel periapical radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: bone-level implant planting of ITI system (straumann) placed with conventional 2 stage surgery followed by cemented fixed prosthesis

Category

Treatment - Surgery

2

Description

Intervention group: tissue-level implant planting of ITI system (straumann) placed with conventional 2 stage surgery followed by cemented fixed prosthesis

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

dental office

Full name of responsible person

dr. Mehrdad Dehghanpour

Street address

Saadat abad

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22439780081

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mdmehrdad26@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr Zarghi

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Daneshjou blvd

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22439780

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr Mehrdad Dehghanpour

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Daneshjou blvd

City

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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Position

professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

the amount of marginal bone loss for each of patients will be revealed

When the data will become available and for how long

from the june of 2022

To whom data/document is available

no limitation

Under which criteria data/document could be used

no limitation

From where data/document is obtainable

to data update agent

What processes are involved for a request to access data/document

from 1 to 6 months after request

Comments