

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Investigating the effect of dedicated healing abutments on clinical and radiographic factors of immediate implants in molar areas after six months

Protocol summary

Study aim

Comparison of the effect of specific abutments on maintaining alveolar ridge contour in immediate posterior implants

Design

The clinical trial has a control group with two parallel groups, a blind strain, randomly classified in blocks of 4 on 26 patients.

Settings and conduct

Eligible people are selected from the patients of Tehran Azad Dental School. Before surgery, a complete jaw mold is prepared. The tooth is extracted and the implant is placed. the control group: Conventional Healing Abutment is placed, the other group: Customized Healing Abutment is placed in the form given by the composite that formed. Recall session 6 months after the surgery, molding is done and a plaster cast is cast. A gauge is used to measure the width of the ridge. a parallel radiograph is prepared on the day of surgery and a radiograph 6 months after surgery. The amount of bleeding on probing and probing pocket depth is evaluated after 6 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: presence of hopeless molar teeth No periodontal disease and decay Complete oral plaque score and bleeding below 20% Agreeing with research condition Exclusion criteria: Systemic or psychological conditions that are contraindications for implant placement Absence of a healthy bone wall in a tooth socket following tooth extraction Patient non-cooperation Heavy smoker (more than 10 cigarettes per day) Bruxism or other disruptive parafunctional habits Primary Stability below 20

Intervention groups

Intervention group: It is formed with composite around the abutment based on the silent shape. Control group: the abutment without composite is placed in the usual

way.

Main outcome variables

Alveolar ridge width

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040460N10**

Registration date: **2024-01-17, 1402/10/27**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-17, 1402/10/27**

Update count: **0**

Registration date

2024-01-17, 1402/10/27

Registrant information

Name

Nima Nadafpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

n_nadaf@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of dedicated healing abutments on clinical and radiographic factors of immediate implants in molar areas after six months

Public title

Investigating the effect of customized healing piece on alveolar ridge contour

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The presence of hopeless molar teeth in the mandible or maxilla
No periodontal disease and obvious decay
Complete oral plaque score and bleeding below 20%
Agreeing to the conditions of the research and signing the consent form

Exclusion criteria:

Systemic or psychological conditions that are contraindications for implant placement
Absence of a healthy bone wall in a tooth socket following tooth extraction
Patient non-cooperation
heavy smoker
Bruxism or other disruptive parafunctional habits
Primary Stability under 20

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, purpose-based sampling and allocation to 2 groups of case and control are done by randomization using the coin toss method and placement in blocks of 4. In this way, the coin is tossed first, if the same group is chosen twice in a row by chance, the other two choices will definitely be the opposite group. This action is done to fix the error of repeating one coin after another, so that in each group of four there must be two control groups and a case. Since our sample size is 26 people, 13 people are in the control group and 13 people are in the case group. Therefore, after 6 blocks of 4, of the 2 people who remain, the first person is determined by throwing a coin and the second person is added to the opposite group.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a blind strain and the evaluator is not aware of the groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee In Research Faculty of Dentistry, Azad University of Medical Sciences, Tehran

Street address

No 9, 9th Neyestan, Pasdaran Street

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2023-10-14, 1402/07/22

Ethics committee reference number

IR.IAU.DENTAL.REC.1402.096

Health conditions studied**1****Description of health condition studied**

Alveolar ridge width

ICD-10 code

K08.2

ICD-10 code description

Atrophy of edentulous alveolar ridge

Primary outcomes**1****Description**

Alveolar ridge width

Timepoint

At the beginning of the study (before the intervention) and six months after the intervention

Method of measurement

On the cast prepared after molding using a gauge with an accuracy of 10 mm

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: On the day of the surgery, after placing the Osstem brand implant made in South Korea, the healing piece is placed on it, and the surrounding area is shaped with light cure composite in the silent shape of the desired tooth, and the area is sutured.

Category

Treatment - Devices

2

Description

Control group: On the day of the surgery, after placing the Osstem brand implant made in South Korea, only the prefabricated healing piece is placed and the area is sutured.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University dental branch Tehran

Full name of responsible person

Dr. Nima Naddafpour

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No.9, 9th Neyestan Ave, Pasdaran Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

DR. Nima Naddafpour

Position

Periodontist_ assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

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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