Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Customized Healing Abutment and Conventional Healing Abutment on preservation of alveolar ridge contour in immediate posterior implants

Protocol summary

Study aim
The effect of Customized Healing Abutment and Conventional Healing Abutment on preservation of alveolar ridge contour in immediate posterior implants

Design
Clinical trial with control group, with 2 parallel groups, double blinded, randomized on 26 patients. Coin flip will be used for randomization.

Settings and conduct
Patients are selected from the patients of Islamic Azad University Dental Branch and divided into 2 groups based on Coin flip. The clinical supervisor, who is a specialist in periodontics, performs the surgery and doesn't inform the participants, the researcher and the outcome assessor about which group each patient is in.

Participants/Inclusion and exclusion criteria
The inclusion criteria are: The patient has a hopeless tooth. They should not have periodontal disease or significant recession. They should agree the study conditions and sign the testimonial. The exclusion criteria are: The systemic or psychological conditions that are implant placement contraindications. When there is not intact bone wall in dental socket after extraction. The patient is not compliant. They are heavy smoker (more than 10 cigarettes per day) They have bruxism or destructive para-functional habits. The primary stability is below 20.

Intervention groups
For the control group, on the surgery day, after placing the Osstem implant made by south Korea, Conventional Healing Abutment is placed and the region will be sutured. For the intervention group,on the surgery day, after placing the Osstem implant made by south Korea, Customized Healing Abutment is placed and formed to the socket shape of the desired tooth by light cure composite and the region will be sutured.

Main outcome variables
Width of alveolar ridge

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220702055345N1**
Registration date: **2022-07-18, 1401/04/27**
Registration timing: **prospective**

Last update: **2022-07-27, 1401/05/05**
Update count: **1**

Registration date
2022-07-18, 1401/04/27

Registrant information

Name
Elahe Soltani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7770 9604

Email address
elaahesoltaani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-06, 1401/05/15

Expected recruitment end date
2022-10-07, 1401/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Customized Healing Abutment and Conventional Healing Abutment on preservation of alveolar ridge contour in immediate posterior implants

Public title
Effect of Customized Healing Abutment on alveolar ridge contour

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient has a hopeless tooth They should not have periodontal disease or significant recession They should agree the study conditions and sign the testimonial

Exclusion criteria:
The systemic or psychological conditions that are implant placement contraindications There is not intact bone wall in dental socket after extraction The patient is not compliant The patient is a heavy smoker (more than 10 cigarettes per day) The patient has bruxism or destructive para-functional habits The primary stability is below 20

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is done by coin-flip. The customized healing abutment group is considered as heads and the Conventional Healing Abutment group is considered as tails. A coin is tossed and patients are assigned to two random groups.

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
Research ethics committees of Islamic Azad University Dental Branch Tehran Iran

Street address
No. 9 , Neyestan Ave, Pasdaran Blvd

City
Tehran

Province
Tehran

Postal code
1946853314

Approval date
2022-07-02, 1401/04/11

Ethics committee reference number
IR.IAU.DENTAL.REC.1401.060

Health conditions studied

1

Description of health condition studied
Width of alveolar ridge

ICD-10 code
K08.2

ICD-10 code description
Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description
Width of Alveolar Ridge

Timepoint
At the start of the research(before intervention) and 3 months later

Method of measurement
On the cast prepared after impression taken, using a gauge with an accuracy of 0.1 mm

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: On the surgery day, after placing the Osstem implant brand, made in South Korea, the Healing Abutment is placed on it and the light cure composite around it is shaped into the socket shape of the desired tooth and the region will be sutured.

Category
Treatment - Devices

2

Description
Control group: On the surgery day after placing the Osstem implant brand, made in South Korea, only the

Healing Abutment is placed on it and the region will be 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

Street address

No.9 , Neyestan Ave, Pasdaran Blvd

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Email

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

Street address

No.9 , Neyestan Ave, Pasdaran Blvd

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Web page address

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

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available