

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effect of subcrestal implant versus crestal implant on marginal bone loss: a randomized clinical trial

Protocol summary

2022-01-10, 1400/10/20

Study aim

To assess the effect of subcrestal implant versus crestal implant on marginal bone loss

Design

This is a randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

Settings and conduct

This study will be performed in the School of Dentistry in Hamadan city on 28 eligible patients. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 70 years; Candidate for dental implant; Exclusion criteria: Smoking; Systemic disease of bone loss; Uncontrolled diabetes; Keratinized gums; Uncontrolled periodontitis;

Intervention groups

Intervention group: Placing subcortical implant one to two millimeters below the crest bone Control group: Placing cortical implant at the edge of the crest bone

Main outcome variables

Primary outcome: Bone loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N415**
Registration date: **2022-01-10, 1400/10/20**
Registration timing: **prospective**

Last update: **2022-01-10, 1400/10/20**

Update count: **0**

Registration date

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-26, 1400/11/06

Expected recruitment end date

2022-07-21, 1401/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of subcrestal implant versus crestal implant on marginal bone loss: a randomized clinical trial

Public title

Effect of subcrestal implant versus crestal implant on marginal bone loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 20 to 70 years; Candidate for dental implant;

Exclusion criteria:

Smoking; Systemic disease of bone loss; Uncontrolled diabetes; Keratinized gums; Uncontrolled periodontitis;

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-11-27, 1400/09/06

Ethics committee reference number

IR.UMSHA.REC.1400.694

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

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

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

Bone loss

Timepoint

3 an 6 months after implant

Method of measurement

Through radiography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Placing subcortical implant one to two millimeters below the crest bone

Category

Treatment - Surgery

2**Description**

Control group: Placing cortical implant at the edge of the crest bone

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of Dentistry in Hamadan city

Full name of responsible person

Leila Shamsavand Baghdadi

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School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Leila Shahsavand Baghdadi

Position

Dentistry Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Morad Hedayatipanah

Position

Periodontist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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