

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation and comparison of marginal bone loss and patient satisfaction in one- implant retained mandibular overdenture and tow-implant retained mandibular overdenture with immediate functional loading

Protocol summary

Summary

The purpose of this study was to evaluate and compare marginal bone loss and satisfaction of one and two implants retained mandibular overdentures with immediate loading in anterior mandible. A total of twenty edentulous patients whose chief complaints are poor retention and stability in mandibular denture, denture soreness and phonetic problems, will be recruited. The patients should have extracted tooth at least 12 months prior to the study and have good bone for insertion of implant with at least 10mm length and 4mm diameter. The patients will randomly be assigned into one of the two groups: 1) 10 patients will take one implant in position C (Misch). 2) 10 patients will take two implants in position B and D (Misch). Mandibular overdentures will be delivered with proper housing at last 48 hours after implant insertion. Digital radiographs will be made with custom film holders for marginal bone loss evaluation and Visual analogue scale questionnaires will be used to record patient satisfaction, immediately, and 1,3, and 6 months after the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010265029N1**
Registration date: **2011-01-20, 1389/10/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-01-20, 1389/10/30

Registrant information

Name

Fariborz Vafaei

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1824 1961

Email address

fvafoee@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Dental school, Hamadan Medical Science University

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of marginal bone loss and patient satisfaction in one- implant retained mandibular overdenture and tow-implant retained mandibular overdenture with immediate functional loading

Public title

Comparison of one vs two implant overdentures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: using complete denture with looseness problem Exclusion criteria: uncontrolled diabetes, heavy smoking

Age

From **25 years** old to **80 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Hamadan Medical Science University Ethics
Committee

Street address

Pajohesh cross, Hamadan

City

Hamdan

Postal code**Approval date**

2010-09-13, 1389/06/22

Ethics committee reference number

16/35/89445/پ

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

bone loss

ICD-10 code

M85.8

ICD-10 code description

Other specified disorders of bone density and structure

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

cervical bone loss

Timepoint

Immediately and 1, 3, and 6 months after the
intervention

Method of measurement

digital periapical radiography

Secondary outcomes**1****Description**

Patient's satisfaction

Timepoint

Immediately and 1, 3, and 6 months after the
intervention

Method of measurement

VAS

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

Control group: use of two implant in anterior mandible

Category

Rehabilitation

2**Description**

Intervention group: use of one implant in anterior
mandible

Category

Rehabilitation

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

Dental School, Hamadan Medical Science University

Full name of responsible person

Dr Fariborz Vafaee

Street address

Dental school, Pajohesh Cross

City

Hamadan

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

Dental School, Hamadan Medical Science University

Full name of responsible person

Dr Fariborz Vafaee

Street address

Dental school, Pajohesh square

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dental School, Hamadan Medical Science University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dental Dental School, Hamadan Medical Science University

Full name of responsible person

Dr Fariborz Vafaee

Position

Assistant Professor

Other areas of specialty/work

Street address

Dental school, Pajohesh Cross

City

Hamadan

Postal code

Phone

+98 81 1824 1961

Fax

Email

fvafacee@umsha.ac.irfvafacee@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Dental School, Hamadan Medical Science University

Full name of responsible person

Dr Fariborz Vafaee

Position

Assistant Professor

Other areas of specialty/work

Street address

Dental School, Hamadan Medical Science University

City

Hamdan

Postal code

Phone

+98 81 1824 1961

Fax

Email

fvafacee@umsha.ac.irfvafacee@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Dental School, Hamadan Medical Science University

Full name of responsible person

Dr Fariborz Vafaee

Position

Assistant Professor

Other areas of specialty/work

Street address

Dental School, Hamadan Medical Science University

City

Hamedan

Postal code

Phone

+98 81 1824 1961

Fax

Email

fvafacee@umsha.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty