

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of patient satisfaction and treatment success rate of immediate loaded one and two implant-retained mandibular overdenture

Protocol summary

Summary

1- Purpose: the patient satisfaction and treatment success rate of immediate loaded one and two implant retained mandibular overdenture was measured by Visual Analog Scale (VAS) before implant placement and six months and one year after implant placement. 2- Design assignation: Clinical randomized trial study, case group including edentulous patient with complete dentures experience received mandibular implant retained immediate loaded single implant and controlled groups including edentulous patient with complete dentures experience received mandibular implant retained immediate loaded bilateral implant 3- Material and methods: 20 edentulous patient, ten in case groups and ten in controlled groups who are dissatisfied with their complete dentures retention and function enroll in this study. Each participant completed a baseline questionnaire on retention, masticatory function and general satisfaction which measured with Visual Analog Scale (VAS). Surgical and prosthodontic procedures applied according to standard protocol in two groups. In case groups midline implant and in control groups bilateral implants immediately loaded. Primary and secondary outcomes including satisfactions, implant and mandibular overdenture denture survival measured after six and twelve months. 4- Participants: Participants in both groups twenty edentulous patients with at least six months experience with conventional complete dentures, were selected from respondents to a university dental clinic's request for volunteers. Candidate screened to verify sufficient bone in anterior of mandible and stable medical conditions. 5- Interventions: 1- Implant surgery and placement of three dental implant in anterior mandible, connection of locator abutments and immediately loading of two groups according to the mentioned protocol. 6- Outcomes: Primary outcomes including measurement of participants satisfaction regarding retention of overdentures, function and general satisfaction. Secondary outcomes including

implant and prosthodontics survival.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112198464N1**

Registration date: **2012-07-05, 1391/04/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-05, 1391/04/15

Registrant information

Name

Parsa Atashrazm

Name of organization / entity

Islamic Azad Dental School

Country

Iran (Islamic Republic of)

Phone

+98 21225645713

Email address

p_atashrazm@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University and Doursanteb Company

Expected recruitment start date

2011-07-17, 1390/04/26

Expected recruitment end date

2012-07-15, 1391/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of patient satisfaction and treatment success rate of immediate loaded one and two implant-retained mandibular overdenture

Public title

Patient satisfaction and treatment success rate of implant-retained mandibular overdenture

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: 1- diabetics. 2- heavy smokers. 3- sever systemic problem. Inclusion criteria: 1- minimum of 10 mm bone height in anterior mandible. 2- Edentulous patients. 3- acceptable complete dentures.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **22**

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

Islamic Azad University, Dental Branch, Ethics Committee

Street address

Islamic Azad Dental School ,10th neystan, Pasdaran

City

Tehran

Postal code

1946853314

Approval date

2011-05-20, 1390/02/30

Ethics committee reference number

پ/229/د

Health conditions studied

1

Description of health condition studied

Fully edentulous patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient's satisfaction

Timepoint

Before implant insertion, six and twelve months after implant loading

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Implant survival

Timepoint

From starting piont of treatment to one year

Method of measurement

Observation

2

Description

Overdenture Survival

Timepoint

Six and Twelve months after immeadiate Loading

Method of measurement

Observation

Intervention groups

1

Description

Placement of single implant with immediate loading in intervetion group2-placement of two implants with immediate loading in control group

Category

Treatment - Surgery

2

Description

Off-loading of immediate loaded single implant and delayed loading of bilateral implants in case groups 2- off-loading of immediate loaded bilateral implants and delayed loading of single implants in control groups

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Removable prosthodontics department of Islamic Azad university

Full name of responsible person

Dr. Atashrazm

Street address

10 Neystan, Pasdaran, Islamic Azad University, Dental branch

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic azad University

Full name of responsible person

Dr. Harajie

Street address

10 neyestan, Pasdaran, Islamic azad University, Dental Branch

City

Tehran

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**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

2

Sponsor

Name of organization / entity

Dorsunteb

Full name of responsible person

Mr. Safari

Street address

Unit. 3, First floor, No. 724, Sattar Khan Ave

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Dorsunteb

Proportion provided by this source**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

Islamic Azad University, Dental Branch

Full name of responsible person

Parsa Aashrazm

Position

Chair of removable prosthodontics department/
Associate professor

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Parsa Atashrazm

Position

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Person responsible for updating data

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Position

Post graduate student

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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