

# 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

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##### 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**

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## 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**

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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**

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

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

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Assocaite Professor

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## Person responsible for updating data

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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*