# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jun 2026

## Implant stability with and without platelet-rich fibrin in patients with tooth loss: a randomized clinical trial

### Protocol summary

**Study aim**
To determine the implant stability with and without platelet-rich fibrin in patients with tooth loss

**Design**
This a randomized clinical trial, phase II, in which 30 eligible patients will be randomly assigned to the intervention and control groups

**Settings and conduct**
The eligible patients with at least two teeth lost who will refer to School of Dentistry during the study period will be enrolled in the trial

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age of 18 to 60 years Having at least 2 teeth lost Enough remaining bone volume for receiving the implant with at least diameter of 4 mm and length of 11.5 mm Exclusion criteria: Any lesion in the oral cavity Using immunosuppressive drugs Liver, blood, or renal diseases Pregnancy

**Intervention groups**
Intervention group: The implant with at least diameter of 4 mm and length of 11.5 mm with platelet-rich fibrin Control group: The implant with at least diameter of 4 mm and length of 11.5 mm without platelet-rich fibrin

**Main outcome variables**
Primary outcome: Implant stability immediately after surgery and 1 and 4 weeks after that through physical examination

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20120215009014N213**
Registration date: **2018-03-15, 1396/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-15, 1396/12/24**
Update count: **0**

**Registration date**
2018-03-15, 1396/12/24

**Registrant information**

**Name**
Jalal Poorolajal

**Name of organization / entity**
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-03-01, 1396/12/10

**Expected recruitment end date**
2018-09-22, 1397/06/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Implant stability with and without platelet-rich fibrin in patients with tooth loss: a randomized clinical trial

**Public title**
Implant stability with and without platelet-rich fibrin in patients with tooth loss

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age of 18 to 60 years Having at least 2 teeth lost Enough remaining bone volume for receiving implant with at least diameter of 4 mm and length of 11.5 mm
**Exclusion criteria:**
Any lesion in oral cavity Using immunosuppressive drugs Liver, blood, or renal diseases Pregnancy

**Age**
From **18 years** old to **60 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **0**
Two teeth loss in every patient will be randomly assigned to the intervention and control groupس using the tossing coin
Actual sample size reached: **30**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Random assignment of the patients to the intervention and control groups through tossing coin

**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**
2018-02-24, 1396/12/05

**Ethics committee reference number**
IR.UMSHA.REC.1396.817

## Health conditions studied

### 1

**Description of health condition studied**
Implant stability

**ICD-10 code**
M27.6

**ICD-10 code description**
Endosseous dental implant failure

## Primary outcomes

### 1

**Description**
Implant stability

**Timepoint**
Immediately after surgery and 1 and 4 weeks after that

**Method of measurement**
Through physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: The implant with at least diameter of 4 mm and length of 11.5 mm with platelet-rich fibrin

**Category**
Treatment - Devices

### 2

**Description**
Control group: The implant with at least diameter of 4 mm and length of 11.5 mm without platelet-rich fibrin

**Category**
Treatment - Devices

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
School of Dentistry

**Full name of responsible person**
Dr Ali Ghamari

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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**
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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**
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**
Dr Ali Ghamari
**Position**
Resident of Periodontics
**Latest degree**
Medical doctor
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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