

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Implant stability with and without platelet-rich fibrin among smokers: a randomized clinical trial

#### Protocol summary

##### Study aim

To determine the implant stability with and without platelet-rich fibrin among smokers

##### Design

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

##### Settings and conduct

The eligible smokers who will refer to School of Dentistry of Hamadan University during the study period will be enrolled in the trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 60 years; Smoker; 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; Using alcohol; 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: **IRCT20120215009014N211**

Registration date: **2018-03-12, 1396/12/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-12, 1396/12/21**

Update count: **0**

##### Registration date

2018-03-12, 1396/12/21

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-20, 1396/10/30

##### Expected recruitment end date

2018-04-20, 1397/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Implant stability with and without platelet-rich fibrin among smokers: a randomized clinical trial

##### Public title

Implant stability with and without platelet-rich fibrin among smokers

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age of 18 to 60 years Smoker 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  
Using alcohol Liver, blood, or renal diseases Pregnancy

**Age**

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

**Gender**

Both

**Phase**

2

**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: **30**

Two teeth loss in every patient will be randomly assigned to each implant. In other words, each patient will be its own control.

**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**

2018-01-13, 1396/10/23

**Ethics committee reference number**

IR.UMSHA.REC.1396.717

**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**

Sara Ebrahimi

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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**

Sara Ebrahimi

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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**

Sara Ebrahimi

**Position**

Student of Dentistry

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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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**Email**

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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