

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Radiographic and histologic comparison of changes in dental sockets grafted with LPRF and sockets without intervention a randomized controlled clinical trial study

#### Protocol summary

##### Study aim

Comparison of Histologic and Radiographic changes in sockets grafted with leukocyte-Platelet Rich Fibrin(LPRF) and sockets without intervention after tooth extraction

##### Design

Single blind two arm parallel group randomized clinical trial study with blinded outcome assessment

##### Settings and conduct

The patients who need extraction of non-molar teeth and referred to implantology department of Tehran University of Medical sciences. the teeth in both groups will have been atraumatically extracted. after extraction and eight weeks later Cone Beam Computed Tomography(CBCT) will perform. Histologic biopsy will obtain in surgery day.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient who need to extraction of nonmolar teeth-at least patient should be 18 years old-lack of any systemic disease-patient should not use any immunosuppressive drug, corton and any drug that can affect the bone metabolism-intact socket or sockets which have less than 50% dehiscence Exclusion criteria: Over than 25 %plaque index-periodontitis-pregnant women-teeth with acute or chronic periapical lesions-traumatic tooth extraction

##### Intervention groups

In both groups the teeth will atraumatically extracted. in test group we will prepare four 10 ml tube of patient blood for obtaining LPRF. the tubes will have been centrifuged with 2700 rpm for 12 minutes.the LPRF clots will have been inserted in socket and then the socket entrance will have been sutured with mattress suture. In control groups after tooth extraction the socket entrance will have been sutured with mattress suture. In both groups immediately after tooth extraction and after 8 weeks the CBCT radiography will have been prepared. in implant surgery day a Trephine bur will have been used as a initial bur and histologic biopsy will be obtained

#### Main outcome variables

Vertical and horizontal edentulous ridge changes New bone formation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160815029369N2**

Registration date: **2019-07-27, 1398/05/05**

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

Last update: **2019-07-27, 1398/05/05**

Update count: **0**

##### Registration date

2019-07-27, 1398/05/05

##### Registrant information

##### Name

Seyyed Yousof Mousavi Salehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6603 2482

##### Email address

sy-mousavis@student.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-05, 1398/03/15

##### Expected recruitment end date

2019-10-05, 1398/07/13

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Radiographic and histologic comparison of changes in dental sockets grafted with LPRF and sockets without intervention a randomized controlled clinical trial study

**Public title**

Evaluation of blood components on healing of extracted teeth site

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patient should be at least 18 years old Lack of any systemic disease Patient should not use any immunosuppressive drug, corton and any drug that can affect the bone metabolism Intact socket or sockets which have less than 50% dehiscence

**Exclusion criteria:**

Over than 25 %plaque index Periodontitis Pregnant women Teeth with acute or chronic peri-apical lesions Traumatic tooth extraction

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **26**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

with regard to simple randomization method we make 2 groups consist of test and control then we wrote them on 26 rolled paper and put them in a basket. each patient take a paper from basket and so her/his group will appear.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The persons who analyse the radiographic image and histologic biopsy do not know about each sample group(test or control)

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

the ethics committee Tehran University of Medical Sciences

**Street address**

Dentistry faculty of Tehran University of Medical Sciences ,Amirabad , North Kargar street

**City**

Tehran

**Province**

Tehran

**Postal code**

1343856134

**Approval date**

2019-01-13, 1397/10/23

**Ethics committee reference number**

IR.TUMS.DENTISTRY.REC.1397.153

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

ridge preservation

**ICD-10 code**

Z40.9

**ICD-10 code description**

Encounter for prophylactic surgery, unspecified

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

changes in ridge height and width

**Timepoint**

Measuring of ridge width and height immediately and 8 weeks after extraction

**Method of measurement**

radiographic analysis will have been performed on DICOM file

**2****Description**

New bone formation

**Timepoint**

New bone formation in histologic view 8 weeks after extraction

**Method of measurement**

Histologic evaluation with Microbin software .

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

ridge width in 25,50 and 75 % of socket depth.

**Timepoint**

immediately after tooth extraction and 8 weeks later

**Method of measurement**

evaluation on DICOM file

**2**

**Description**

height of buccal plate

**Timepoint**

immediately after tooth extraction and 8 weeks later

**Method of measurement**

evaluation on DICOM file

**3**

**Description**

height of lingual plate

**Timepoint**

immediately after tooth extraction and 8 weeks later

**Method of measurement**

evaluation on DICOM file

**Intervention groups**

**1**

**Description**

Intervention group: the teeth will have been extracted atraumatically with Periotome. four 10 ml tubes of blood will have been taken from patients and Leukocyte platelet fibrin will have been prepare with 2700 rpm 12 minutes protocol(Intraspine. Intralock .florida. USA). LPRF clots inserted in site of extraction and gently packed.we suture the entrance of socket with 5.0 nylon with mattress suture.we prescribe Iboprofen 400mg tid for 2 days and Cholorhexidine mouth rinse bid for one week. after one week the suture will have been removed. CBCT radiography will have been taken immediately after and 8 weeks later. in day of implant placement the histologic biopsy will have been obtained from site of implant placement using Trephine bur as a initial drill.

**Category**

Treatment - Surgery

**2**

**Description**

Intervention group: the teeth will be extracted atraumatically with Periotome. we suture the entrance of socket with 5.0 nylon with mattress suture.we prescribe Iboprofen 400mg tid for 2 days and Cholorhexidine mouth rinse bid for one week.after one week the suture will have been removed. CBCT radiography will have been taken immediately after and 8 weeks later. in day of implant placement the histologic biopsy will have been obtained from site of implant placement using Trephine bur as a initial drill.

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Implantology department of Tehran university of medical sciences

**Full name of responsible person**

Yousof Mousavi

**Street address**

Dentistry faculty of Tehran university of Medical sciences,Amirabbad,North Kargar street

**City**

Tehran

**Province**

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**Postal code**

1343856134

**Phone**

+98 21 8835 1178

**Email**

ym.mousavi@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Yousof Mousavi

**Street address**

Tehran University of Medical sciences, Ebne sina street

**City**

Tehran

**Province**

Tehran

**Postal code**

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**Phone**

+98 21 8835 1178

**Email**

ym.mousavi@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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

+98 21 8835 1178

## Email

ym.mousavi@gmail.com

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Yusof Mousavi

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dentistry

#### Street address

Dentistry Faculty of Tehran University of Medical Sciences, Amirababd, North Kargar street

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Yusof Mousavi

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Resident

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Yusof Mousavi

#### Position

Resident

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Dentistry

#### Street address

Dentistry Faculty of Medical Sciences, Amirabad, North Kargar street

#### City

Tehran

#### Province

Tehran

#### Postal code

1343856134

#### Phone

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

there is no more information 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