Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

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Iran (Islamic Republic of)

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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 tiral 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

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

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Yousof Mousavi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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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)
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