Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

Evaluation of the effect of LPRF on the stiffness of the implant – bone interfce and primary stability in implants placed in edentulous posterior maxilla

Protocol summary

Study aim

Evaluation and comparison of initial stability and strength of the implant-bone interface in posterior maxillary implants and comparison of the marginal bone loss around the implant in parallel periapical radiography between the two groups of test and control

Design

15 patients who needed at least two implants in the posterior maxilla entered the study. During the surgery implants group were randomly determined by sealed envelope method and then Clinical and radiographic evaluations were performed in both groups during a 3-month follow-up period. The study was single blinded.

Settings and conduct

The study location was the implant department of the School of Dentistry, Tehran University of Medical Sciences. In each patient, in one surgical session, two implants were inserted. the examiner were blinded during the follow-up period. After a three-month follow-up period Periapical radiograph was taken.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients (over 18 years), systemically healthy, plaque index under 25%, there should be sufficient bone width and height in the desired area, there should be sufficient mesiodistal and interocclusal space. Exclusion criteria: Diabetes or any metabolic disease affecting bone metabolism, Pregnant women, People taking immunosuppressive drugs or corticosteroids, People with a history of radiotherapy or chemotherapy, and Patients with a history of surgery, bone grafting, or sinus floor augmentation.

Intervention groups

Placing blood derivatives on implants inserted in posterior maxilla and its effects on the initial stability and interface strength of implants compared to the implants without placing blood derivatives on the similar site.

Main outcome variables

Implant Stability Quotient ; Marginal bone loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200624047906N1**
Registration date: **2020-12-22, 1399/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-22, 1399/10/02**
Update count: **0**

Registration date

2020-12-22, 1399/10/02

Registrant information

Name

Meshkat Naeimi darestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4279 4342

Email address

meshkat_dnt@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of LPRF on the stiffness of the implant – bone interfce and primary stability in implants placed in edentulous posterior maxilla

Public title
Evaluation of the effect of LPRF on the stiffness and stability of implants placed in posterior maxilla

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults (over 18 years old) healthy persons overall plaque index under 25% sufficient bone volume in vertical and horizontal lines sufficient mesiodistal and interocclusal space

Exclusion criteria:
Diabetic patients or any other disease that affects bone metabolism pregnant patients people who use corticosteroids or other immune system suppressors people who got bone graft or sinus floor augmentation previously

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **2**
In each patient, a sample is defined for the intervention group and a sample for the control group.

Randomization (investigator's opinion)
Randomized

Randomization description
At the beginning of the surgery, the test and control group is determined for each patient by using sealed envelopes (draw a pocket).

Blinding (investigator's opinion)
Single blinded

Blinding description
After surgery and suturing the area;The examiner clinician is asked to measure the ISQ of both the test and control sites and to obtain standard PA radiographs of both site and to determine the required values in them.It should be noted that after surgery, it is not possible to distinguish between the two groups, so the examiner is blinded to the study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, dental school,North karkar Ave.,Amir abad.,Tehran Town

City
Tehran

Province
Tehran

Postal code
1343856134

Approval date
2020-10-28, 1399/08/07

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1399.138

Health conditions studied

1

Description of health condition studied
Implant placement in edentulous site

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
ISQ score

Timepoint
On the day of surgery immediately after implant placement and in the week 2-4-6-8-12 after surgery

Method of measurement
Osstell device

2

Description
The amount of marginal bone loss around implant

Timepoint
On the day of surgery immediately after implant placement and 12 weeks later

Method of measurement
Parallel periapical radiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Placement of LPRF membrane obtained from 20 cc of patient venous blood on the implant before placement in bone during surgery
Category
Treatment - Surgery

2

Description
Control group: Implant placement in the bone in the usual way and without any additional intervention
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Implant Department, School of Dentistry, Tehran University of Medical Sciences
Full name of responsible person
Meshkat naeimi darestani
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School of Dentistry, Tehran University of Medical Sciences., North kargar Ave, Amir Abad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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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
Meshkat naeimi darestani
Position
Resident
Latest degree
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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