

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Evaluation of the effect of LPRF on the stiffness of the implant - bone interface 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 interface 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

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

Meshkat naeimi darestani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

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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