

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The Comparison of clinical, radiographic and histological outcomes of socket preservation following tooth extraction using allograft with and without injectable platelet rich fibrin

Protocol summary

Study aim

Comparison of clinical, radiographic and histological results of the use of Allograft grafting material with and without I-PRF in maintaining socket After tooth extraction

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized on 15 patients, and random function of Excel software used for randomization.

Settings and conduct

Patients refer to the department of Shahid Beheshti School of Dentistry for tooth extraction and implant placement in 1401. The sampling method in the present study is "total enumeration". The number of patients included in this study is estimated to be 10. The outcome assessors and patients were blinded to the interventions.

Participants/Inclusion and exclusion criteria

Entry criteria: 1) The patient must be over 18 years old 2) A single-rooted tooth that needs to be pulled and replaced with dental implant restoration. 3) Remaining bone support more than 50% Exit criteria: 1) The presence of any systemic disease or disease that affects bone healing 2) Taking any medicine that is effective on bone healing 3) Presence of severe or uncontrolled systemic disease 4) Pregnancy 5) daily consumption of 10 cigarettes or more 6) History of radiotherapy 7) Having a contraindication for implant placement 8) Using any prosthesis in the intervention site 9) Need for antibiotic prophylaxis 10) Presence of widespread infection near the intervention site

Intervention groups

1) Allograft group without I-PRF substance 2) Allograft group plus I-PRF. In the first group, socket is filled with allograft material and covered with collacone. cross stitch (figure of eight) will be applied by means of 4-0 Vicryl absorbable thread. In the second group, the socket is filled with I-PRF and allograft material and covered with collacone.

Main outcome variables

alveolar socket width; amount of vital bone; radiographic evaluation; vertical height of alveolar socket

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221227056937N1**

Registration date: **2023-01-12, 1401/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-12, 1401/10/22**

Update count: **0**

Registration date

2023-01-12, 1401/10/22

Registrant information

Name

Masoud Hatami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of clinical, radiographic and histological outcomes of socket preservation following tooth extraction using allograft with and without injectable platelet rich fibrin

Public title

Investigating the effect of liquid PRF in maintaining dental socket

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient must be over 18 years old single root tooth that needs to be pulled and replaced with dental implant restoration. Remaining bone support more than 50%

Exclusion criteria:

The presence of any systemic disease or disease that affects bone healing Taking any medicine that is effective on bone healing Existence of severe or uncontrolled systemic disease Pregnancy Daily consumption of 10 cigarettes or more History of radiotherapy Having a contraindication for implant placement Using any prosthesis in the intervention site Need for antibiotic prophylaxis Presence of widespread infection near the intervention site

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

Implant candidate teeth that meet the conditions of entry into the study

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Not informing the patient about the exact type of possible practical measures for each group (of course, after giving the necessary explanations and clarifying the issue and obtaining an informed consent) and not knowing the outcome finder about the type of therapeutic intervention performed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran

Street address

Shahid Chamran Highway-Yemen St.-Daneshjo Blvd.- Shahid Beheshti Faculty of Dentistry, Tehran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2022-11-14, 1401/08/23

Ethics committee reference number

IR.SBMU.DRC.REC.1401.066

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

Maintaining the socket dimensions of the tooth after tooth extraction for implant treatment

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

alveolar socket width: the width of the alveolar bone in the midbuccal region from the buccal side to the lingual side of the drawn tooth.

Timepoint

At the beginning of the study (before the start of the intervention) and 3 months after the intended treatment

Method of measurement

The digital caliper calculates the width of the alveolar bone in the midbuccal area from the buccal to the lingual side of the extracted tooth with an accuracy of 0.01 mm.

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

radiographic evaluation

Timepoint

The beginning of the study (before the intervention) and 3 months after the intervention

Method of measurement

By using CBCT device The alveolar socket is evaluated in the buccolingual and mesiodistal dimensions at 1, 3 and 5 mm sections.

2

Description

amount of vital bone

Timepoint

At the beginning of the study (before the start of the intervention) and 3 months after the intervention

Method of measurement

Presence of osteocyte and osteoblast along with bone trabeculae in bone tissue through light microscope evaluation

3

Description

socket vertical height in the midbuccal region

Timepoint

At the beginning of the study (before the start of the intervention) and 3 months after the intervention

Method of measurement

The height of the alveolar bone in the midbuccal area from the CEJ of the adjacent tooth to the edge of the alveolar crest was measured with a digital calliper to the accuracy of 0.01 mm.

Intervention groups

1

Description

Control group: Allograft group without I-PRF substance. the socket is filled with allograft material (Itp Regen) and covered with collacone. Then, a cross stitch (figure of eight) will be applied with a 4-0 vicryl absorbable thread

Category

Treatment - Surgery

2

Description

Intervention group: Allograft group plus I-PRF

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Faculty of Dentistry, Tehran

Full name of responsible person

Masoud Hatami

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No. 9, Unit 4, Sobakro Karimi Alley, North Eskandari St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Hadi Ghasemi

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Web page address

<http://www.drc.sbmu.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

masoud Hatami

Position

resident

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry

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

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Fax**Email****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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available