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 rand 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;radigraphic 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)
Phone
+98 21 6694 0647
Email address
hatamimassod@yahoo.com

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 deviceThe 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 alvelar 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
Street address
No. 9, Unit 4, Sobakro Karimi Alley, North Eskandari St.
City
Tehran
Province
Tehran
Postal code
1419764675
Phone
+98 21 6694 0647
Email
Hatamimassod@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hadi Ghasemi
Street address
Tehran - Shahid Chamran Highway, Evin Blvd., Shahid Beheshti Dental College
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2241 3897
Fax
+98 21 2242 7753
Email
research.ids@sbmu.ac.ir
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
Street address
No. 9, Unit 4, Sobakro Karimi Alley, North Eskandari St.
City
Tehran
Province
Tehran
Postal code
1419764675
Phone
+98 21 6694 0647
Email
Hatamimassod@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masoud Hatami
Position
Resident
Latest degree
Subspecialist
Other areas of specialty/work
Dentistry
Street address
Azadi street ,North Eskandari street,Sabokro Karimi alley,block 9
City
Tehran
Province
Tehran
Postal code
1419764675
Phone
+98 21 6694 0647
Fax
Email
Hatamimassod@yahoo.com

Person responsible for updating data

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
Street address
Azadi street ,North Eskandari street,Sabokro Karimi alley,block 9
City
Tehran
Province
Tehran
Postal code
1419764675
Phone
+98 21 6694 0647
Fax
Email
Hatamimassod@yahoo.com

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