

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

comparison of histologic, clinical and radiographic results of post extraction ridge preservation using xenogenic bone material with/without A-PRF

Protocol summary

Study aim

The effect of simultaneous application of Bio-Oss and A-PRF on reducing the Period of treatment in Socket preservation.

Design

clinical trial, 2 sided blind, with control group and randomized. 10 sample in each group. (total sample size is 20) randomization of intervention sequence is done with 20 letter pocket containing equal number of control and test group titles.

Settings and conduct

after optimal anesthesia, tooth is extracted and with minimum flap reflection using less traumatic technique. Bio-Oss is applied to overfill the socket. Bio-Gide membrane is used to cover the socket. flap is sutured with 4-0 vicryl suture. in test group A-PRF is mixed with Bio-Oss before it is applied. after 3 month biopsy is harvested and implant is inserted.

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study 1 - aged over 18 years 2. Healthy patients ASA 1 and 2 3. Periodontal health 4. Bone conditions : at least 50% of the bone support remain after the tooth is extracted. 5 - absence of any infection or periapical lesion 6 - absence of any uncontrolled systemic disease that compromise the healing process, such as uncontrolled diabetes exclusion criteria for the study 1 - Patients with ASA III status or above 2. The presence of any uncontrolled systemic disease disrupts the recovery process, such as uncontrolled diabetes 3-Cigarette 4. Use of immunosuppressive drugs 5 - Radiotherapy history 6- pregnancy 7 - Removable prosthesis in the treatment area or adjacent to the target area 8 - spreading infection adjacent to the target area

Intervention groups

- Group 1: control: Biomaterial + barrier membrane •
- Group 2: Test : Biomaterial + A-PRF + barrier Membrane

Main outcome variables

Ridge height, Ridge width, soft tissue closure time, new bone formation related to remnant bio material particles

General information

Reason for update

Acronym

A-PRF = Advanced platelet rich fibrin

IRCT registration information

IRCT registration number: **IRCT20180416039329N1**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **retrospective**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Armin Mirfasihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2239 1635

Email address

arminmirfasihi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

2019-01-10, 1397/10/20
Actual recruitment end date
2019-04-09, 1398/01/20
Trial completion date
2019-07-06, 1398/04/15

Scientific title

comparison of histologic, clinical and radiographic results of post extraction ridge preservation using xenogenic bone material with/without A-PRF

Public title

comparison of histologic, clinical and radiographic results of post extraction ridge preservation using xenogenic bone material with/without A-PRF

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

aged over 18 years Periodontal health Healthy patients and ASAs 1 and 2, according to the American Cancer Society Association's classification system absence of any infection or periapical lesion Bone conditions such that at least 50% of the bone support remains after the tooth is extracted.(Necessity of Radiographic evaluation before surgery) absence of any uncontrolled systemic disease that complicates the healing process, such as uncontrolled diabetes

Exclusion criteria:

Patients with ASA III status or above presence of any uncontrolled systemic disease that complicates the healing process, such as uncontrolled diabetes smoker Use of immunosuppressive drugs Radiotherapy history pregnancy Removable prosthesis in the treatment area or adjacent to the dental socket area spreading infection adjacent to the target area

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

random allocation software was used for simple randomization. after allocation in 2 groups with 10 participants, concealed in sequentially numbered, sealed, opaque envelopes were used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of shahid beheshti university of medial sciences

Street address

velenjak ave. chamran highway

City

tehran

Province

Tehran

Postal code

1983963113

Approval date

2018-02-12, 1396/11/23

Ethics committee reference number

IR.SBMU.RIDS.REC.1396.562

Health conditions studied

1

Description of health condition studied

ridge preservation-xenograft-Bio-Oss-PRF

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

bone height

Timepoint

base time- 3 month

Method of measurement

CBCT (radiographic evaluation)

2

Description

Bone width

Timepoint

base time- 3 month

Method of measurement

CBCT (radiographic evaluation)

3

Description

ratio of 1-new bone formation to 2-remnant particles to 3-other non mineralized tissues

Timepoint

base time- 3 month

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Bio-Oss group: CBCT radiography is taken. after optimum local anesthesia, tooth is extracted using less traumatic approach and minimum reflection of the flap. Bio-Oss is prepared with conventional method and is applied to overfill the socket. Bio-Gide membrane is used to cover the socket completely. flap is sutured with 4-0 vicryl and figure of 8 technique. 3 month later CBCT radiography is taken again, Biopsy is harvested before the implant placement.

Category

Treatment - Surgery

2

Description

Intervention group: Bio-Oss + A-PRF group: CBCT radiography is taken. after optimum local anesthesia, tooth is extracted using less traumatic approach and minimum reflection of the flap. Bio-Oss is mixed with A-PRF (by centrifuging the patient's blood) and is applied to overfill the socket. Bio-Gide membrane is used to cover the socket completely. flap is sutured with 4-0 vicryl and figure of 8 technique. 3 month later CBCT radiography is taken again, Biopsy is harvested before the implant placement.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

دانشکده دندان پزشکی شهید بهشتی

Full name of responsible person

دکتر آرمین میرقصیحی

Street address

no. 30-takhti street-fereshteh ave. vali asr street

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1965745411

Phone

+98 21 2203 5062

Email

arminmirfasihi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

معاونت پژوهشی دانشکده دندانپزشکی شهید بهشتی

Full name of responsible person

Dr.azita tehranchi

Street address

velenjak ave. chamran highway

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tehran

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1983963113

Phone

+98 21 2217 5351

Email

arminmirfasihi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

معاونت پژوهشی دانشکده دندانپزشکی شهید بهشتی

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

Dr.Armin mirfasihi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

periodontology

Street address

no 30-takhti street-fereshteh street-vali asr ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr.Armin mirfasihi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

all information is accessible

When the data will become available and for how long

after publication

To whom data/document is available

all related fields

Under which criteria data/document could be used

bailment principles

From where data/document is obtainable

arminmirfasihi@yahoo.com

What processes are involved for a request to access data/document

sending request via email-evaluate-sending the information(1 month)

Comments