

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the effect of i-prf and Allograft bone substitute combination in bone regeneration around immediate implants with buccal bone dehiscence

Protocol summary

Study aim

determination of implant stability, alveolar ridge dimensions, and bone density immediately and 6 months after implants with the use of injectable platelet-rich fibrin and Allograft or Allograft solely.

Design

A phase 2 clinical trial with the control group, with parallel groups, without blinding on 20 patients

Settings and conduct

After the evaluation of the patient's radiography and inclusion criteria in patients in the hospital of Mashhad University of Medical Sciences in need of immediate implants in the anterior region, patients will be divided into two groups with respect to the patient's age and sex, and the position of the implant. informed consent will be taken from patients. 10 ml of whole blood will be taken from the intervention group and i-prf will be made and combined with allograft for filling the buccal gap. 2 CBCT will be taken from the implant region immediately and 6 months after implantation. bone density and dimension of buccal bone, and implant stability will be measured. outcome assessors will be blinded.

Participants/Inclusion and exclusion criteria

Including criteria: 1) one root tooth (mandible or maxilla) because of trauma, decay, root degeneration 2) Limitation of 20-year-old 3) space between sucket and fixture is equal to or more than 2 mm in one-third of the cranial sucket Excluding criteria: 1) Severe rage atrophy 2) active infection (periodontitis, or mucosal infection) 3) radiotherapy diseases or chemotherapy

Intervention groups

Intervention group: 10 patients who after implant, allograft with platelet-rich fibrin was used in the regeneration of buccal defect. Control group: 10 patients who after implant, allograft without platelet-rich fibrin was used in the regeneration of buccal defect

Main outcome variables

implant stability, bone density, dimensions of buccal bone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220407054448N1**

Registration date: **2022-05-08, 1401/02/18**

Registration timing: **retrospective**

Last update: **2022-05-08, 1401/02/18**

Update count: **0**

Registration date

2022-05-08, 1401/02/18

Registrant information

Name

Mahsa Ahmadi Shadmehri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3867 4195

Email address

mhs.ahmadishadmehri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-09, 1400/12/18

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

2022-03-10, 1400/12/19

Actual recruitment end date

2022-04-14, 1401/01/25

Trial completion date
empty

Scientific title
Evaluation of the effect of i-prf and Allograft bone substitute combination in bone regeneration around immediate implants with buccal bone dehiscence

Public title
Platelet-rich fibrin in immediate implants with buccal bone defect

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
hopeless single root teeth extracted due to trauma, caries, resorption and root fracture age over 20 years old good oral hygiene : FMBS,FMPS < 25% Buccal gap between socket wall and fixture more than 2 mm plus a small dehiscence defect in buccal healthy soft tissue
Exclusion criteria:
severe atrophy of ridge active infection (on periodontium or mucosa) patient with history of radiotherapy or chemotherapy use of alcohol or cigarette more than 10 pieces a day patient with systemic disorders (uncontrolled diabetes, autoimmune disorders, etc..) pregnancy patient with bone, or hematologic disorders presence of periapical pathology which involves adjacent teeth

Age
From **20 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)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee

Name of ethics committee
ethics committee of islamic azad university of isfahan (khorasgan Branch)

Street address
arghavanieh blv

City
isfahan

Province
Isfahan

Postal code
81551-39998

Approval date
2022-03-09, 1400/12/18

Ethics committee reference number
IR.IAU.KHUISF.REC.1400.355

Health conditions studied

1
Description of health condition studied
Buccal bone defect

ICD-10 code
M27.8

ICD-10 code description
Other specified diseases of jaws

Primary outcomes

1
Description
dimension of buccal bone plate

Timepoint
6 months from immediate implantation

Method of measurement
cone beam computed tomography (CBCT)

2
Description
bone density

Timepoint
6 months from immediate implantation

Method of measurement
cone beam computed tomography (CBCT)

3
Description
implant stability value

Timepoint
6 months from immediate implantation

Method of measurement
periost device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 patients who after implanting, allograft with platelet-rich fibrin was used in buccal defect regeneration.

Category

Treatment - Surgery

2

Description

Control group: 10 patients who after implanting, allograft without platelet-rich fibrin was used in buccal defect regeneration.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

periodontics department of dental school of islamic azad university of isfahan (khorasgan branch)

Full name of responsible person

vahid esfahanian

Street address

islamic azad university of isfahan(khorasgan branch) arghavanie ave., Jey blv., isfahan, Iran

City

isfahan

Province

Isfahan

Postal code

81551-39998

Phone

+98 936 668 9455

Email

mhs.ahmadishadmehri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

vahid esfahanian

Street address

islamic azad university of isfahan (khorasgan branch),.arghavanieh ave., jey blv., isfahan.

City

isfahan

Province

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Postal code

81551-39998

Phone

+98 936 668 9455

Email

mhs.ahmadishadmehri@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

vahid esfahanian

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

islamic azad university of isfahan., arghavanie ave., Jey blv., isfahan.

City

isfahan

Province

Isfahan

Postal code

81558-39998

Phone

+98 31 3500 2141

Email

mhs.ahmadishadmehri@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

vahid esfahanian

Position

assistant professor

Latest degree

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Dentistry

Street address

islamic azad university of isfahan., arghavanie ave.,
Jey blv., isfahan.

City

isfahan

Province

Isfahan

Postal code

81558-31998

Phone

00983235002141

Email

mhs.ahmadishadmehri@gmail.com

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

Islamic Azad University

Full name of responsible person

mahsa ahmadi shadmehri

Position

postgraduate student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

no.59- 5th sadaf street- vakilabad blv

City

mashhad

Province

Razavi Khorasan

Postal code

81558-31998

Phone

+98 51 3867 4195

Email

mhs.ahmadishadmehri@gmail.com

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

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

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

data of primary outcomes collected via CBCT or periostest will be shared if necessary.

When the data will become available and for how long

data will be shared 6 months after the publication of the study.

To whom data/document is available

data will be available for academic institutions and researchers who ask for.

Under which criteria data/document could be used

data will be available for researchers who need them for similar researches or systematic review and meta-analysis.

From where data/document is obtainable

researchers can get the data via Email:
mhs.ahmadishadmehri@gmail.com

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

after sending an email for the data request, data will be posted for the researchers within a week. email:
mhs.ahmadishadmehri@gmail.com

Comments