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 cigarrete 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

isfehan

Province

Isfehan

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

periotest 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Person responsible for updating data

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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
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 periotest 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 avilable for researchers who need them for similar researches or systematic review and meta-anlysis.
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