Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Healing Time on New Bone Formation after Tooth Extraction with Freeze-Dried Bone Allograft

Protocol summary

Study aim

Comparison of Effects between Short-term (3 months, Intervention group) and Long-term (4 months, Control group) of FDBA Allograft on New Bone Formation after Tooth Extraction.

Design

After extraction of the teeth, after a Debridement and complete washing, the Bone graft material is hydrated for 10 minutes with Sterile Saline and then placed in tooth Socket. The Socket is sutured with Nylon 5-0 Thread. Then patients are scheduled to be sampled. After 3 or 4 months, sampling is done by Trephine Bur. The sample is placed in a Neutral 10% Formaldehyde Buffering Solution and will be sent to the Laboratory for data collection.

Settings and conduct

This research is done at the Faculty of Dentistry, Islamic Azad University, Tehran. After removing tooth, the FDBA is placed in the tooth Socket and then the Suture is done by Nylon 5-0 thread. Patients are called up after 3 or 4 months, depending on the group they are in. Bone samples are taken from the target area and sent to the Laboratory for data collection.

Participants/Inclusion and exclusion criteria

Patient inclusion criteria: Single-rooted teeth needing extraction. Patient desiring restoration with a Dental implant. Adequate space for Restoration. Exclusion criteria: Patients not fulfilling inclusion criteria or not compliant with necessary procedural follow-up Pregnancy Active Systemic/Local infection not including Periodontitis Medical conditions or medications known to alter soft tissue or bony healing (Poorly controlled Diabetes Mellitus [DM], Bisphosphonates, Immunosuppressives, etc.Teeth with short roots or roots that were Malpositioned such that the Core Biopsy might include bone along the Socket Wall.

Intervention groups

Tooth extraction is performed on all patients entering the study.

Main outcome variables

New Bone Formation, Residual Graft, Connective Tissue and Inflammation after 3 months and 4 months.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170419033535N4**
Registration date: **2019-01-05, 1397/10/15**
Registration timing: **retrospective**

Last update: **2019-01-05, 1397/10/15**
Update count: **0**

Registration date

2019-01-05, 1397/10/15

Registrant information

Name
omid moghaddas

Name of organization / entity
islamic azad unicersity dental of teh

Country
Iran (Islamic Republic of)

Phone
+98 912 277 6280

Email address
o_moghaddas@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2018-11-15, 1397/08/24

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Healing Time on New Bone Formation after Tooth Extraction with Freeze-Dried Bone Allograft

Public title
Effect of Freeze-Dried Bone Allograft on new bone formation after tooth extraction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Single-rooted teeth needing extraction Patient desiring restoration with Dental implant Adequate space for Restoration
Exclusion criteria:
Patients not fulfilling inclusion criteria or not compliant with necessary procedural follow-up Active Systemic/Local infection not including Periodontitis Medical conditions or medications known to alter soft tissue or bony healing (Poorly controlled Diabetes Mellitus [DM], Bisphosphonates, Immunosuppressives, etc.) Teeth with short roots or roots that were Malpositioned such that the Core Biopsy might include bone along the Socket Wall. Females of childbearing age without Tubal Ligation, Menopause, or Hysterectomy were required to have a Negative Pregnancy Test prior to Surgery. Pregnancy
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Actual sample size reached: **40**
More than 1 sample in each individual
Actual sample size in each individual: **0**
Randomization (investigator's opinion)
Randomized
Randomization description
Dividing the samples completely randomly into two groups of 3 months (Intervention group) and 4 months (Control group) by dropping the coin and hiding the card until the patients were recalled.
Blinding (investigator's opinion)
Double blinded
Blinding description
All individuals involved in this research, such as Clinicians, Outcome Evaluators, Data Analyzers, Safety Committees, and Data Monitoring, have been unaware of the randomization process of samples, and only researchers and therapists in this study have compared the time Sampling and referral of patients are well known.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Dentistry Islamic Azad University of Tehran
Street address
Ninth Neyestan Avenue, Pasdaran Street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1946853314
Approval date
2017-06-18, 1396/03/28
Ethics committee reference number
IR.IAU.DENTAL.REC.1396,12

Health conditions studied

1

Description of health condition studied
Evaluation of bone formation with FDBA after tooth extraction.
ICD-10 code
K08.2
ICD-10 code description
Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description
The amount of Bone Formation
Timepoint
3 months and 4 months
Method of measurement
Calculated by Optical Microscope

2

Description

The amount of Residual Graft

Timepoint

3 months and 4 months

Method of measurement

Calculated by Optical Microscope

3

Description

The amount of Connective Tissue and Inflammation Rate

Timepoint

3 months and 4 months

Method of measurement

Calculated by Optical Microscope

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group includes 20 dental samples need to be extracted and required Implant treatment. The dental socket (after tooth extraction) is filled with FDBA, from Hamanand Saz Baft Kish company, Iran, and its entry is covered with Collagen from brand called Auto Plug. The specimens are randomly divided into this group (3 months) and after the prescribed time, they are called for sampling. The bone sample is taken to examine the condition of the bone and is delivered to the Pathology Laboratory. FDBA (Freeze-Dried bone Allograft) is an Allograft material that is obtained by Minerilizing the cortical bone of the same species, and freezing and drying it. In 1976, FDBA entered periodontal treatments and was considered as an Osteoconductive material.

Category

Treatment - Surgery

2

Description

Control group: This group includes 20 dental samples need to be extracted and required implant treatment. The dental socket (after tooth extraction) is filled with FDBA, from Hamanand Saz Baft Kish company, Iran, and its entry is covered with Collagen from brand called Auto Plug. The specimens are randomly divided into this group (4 months) , and after the prescribed time, they are called for sampling. The bone sample is taken to examine the condition of the bone and is delivered to the Pathology Laboratory. FDBA (Freeze-Dried bone Allograft) is an Allograft material that is obtained by Minerilizing the cortical bone of the same species, and freezing and drying it. In 1976, FDBA entered periodontal treatments and was considered as an Osteoconductive material.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry Islamic Azad University of Tehran

Full name of responsible person

Omid Moghadas

Street address

Ninth Neyestan Avenue, Pasdaran Street, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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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

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
Islamic Azad University

Full name of responsible person
Omid Moghadas

Position
Periodontics professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Ninth Neyestan Avenue, Pasdaran Street, Tehran, Iran.

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Person responsible for scientific inquiries

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Islamic Azad University

Full name of responsible person
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Position
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Latest degree
Specialist

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Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Peyman Nikookar

Position
Dental student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Comparison of short-term effects (3 months, intervention group) and long-term effects (4 months, control group) of FDBA application on Histopathology of bone formation following tooth extraction in patients referring to dental unit of Islamic Azad University of Tehran in 1396-1397.

When the data will become available and for how long
6 months after printing results

To whom data/document is available
All people who need data can apply for them.

Under which criteria data/document could be used
Analyzes that do not harm our data.

From where data/document is obtainable
Faculty of Dentistry Islamic Azad University of Tehran

What processes are involved for a request to access data/document
Visit the Faculty of Dentistry, Islamic Azad University of Tehran and request there, and will access the data within 1 week.

Comments