

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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 Trepine 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.

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

o\_moghaddas@dentaliau.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Arash Azizi

**Street address**

Ninth Neyestan Avenue, Pasdaran Street, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

nkrpeyman@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**

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

**Street address**

Ninth Neyestan Avenue, Pasdaran Street, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

o\_moghaddas@dentaliau.ac.ir

## Person responsible for scientific 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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1946853314

**Phone**

+98 21 2256 4571

**Email**

o\_moghaddas@dentaliau.ac.ir

## 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

**Street address**

Ninth Neyestan Avenue, Pasdaran Street, Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

nkrpeyman@gmail.com

## 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 FDDB 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