

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Effect of healing time on new bone formation after tooth extraction with HA/ $\beta$ -TCP

#### Protocol summary

##### Study aim

Comparison of short-term effects (3 months, case group) and long-term (4 months, control group) of HA/ $\beta$ -TCP on new bone formation; following tooth extraction.

##### Design

After removing of the teeth, after a debridement and complete washing, the bone graft is hydrated for 10 minutes with sterile saline and then placed in the 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 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 HA/ $\beta$ -TCP 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 people 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: **IRCT20180714040460N2**

Registration date: **2018-12-26, 1397/10/05**

Registration timing: **retrospective**

Last update: **2018-12-26, 1397/10/05**

Update count: **0**

##### Registration date

2018-12-26, 1397/10/05

##### Registrant information

##### Name

Nima Nadafpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2256 4571

##### Email address

n\_nadaf@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

2017-10-22, 1396/07/30

##### Actual recruitment end date

2018-11-15, 1397/08/24

##### Trial completion date

empty

### Scientific title

Effect of healing time on new bone formation after tooth extraction with HA/ $\beta$ -TCP

### Public title

Effect of HA/ $\beta$ -TCP on new bone formation after tooth extraction

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### 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. Females of childbearing age without tubal ligation, menopause, or hysterectomy were required to have a negative pregnancy test prior to surgery.

### Age

No age limit

### Gender

Both

### Phase

3

### Groups that have been masked

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

### Sample size

Target sample size: 40

### Randomization (investigator's opinion)

Randomized

### Randomization description

Dividing the samples completely randomly into two groups of case and control by dropping the coin and dividing it into two groups of 3 months (case) and 4 months (control) and hiding the card until the patients were re-referenced.

### 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, Tehran Branch

##### Street address

Tehran, Pasdaran Street, Ninth Neyestan Avenue

##### City

Tehran

##### Province

Tehran

##### Postal code

19585175

#### Approval date

2017-06-18, 1396/03/28

#### Ethics committee reference number

IR.IAU.DENTAL.REC.1396,15

## Health conditions studied

### 1

#### Description of health condition studied

Evaluation of bone formation with HA/ $\beta$ -TCP 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

Amount of Residual graft

#### Timepoint

3 months and 4 months

#### Method of measurement

Calculated by optical microscope

### 3

#### **Description**

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 OSTEON, from Dentium company, Korea, 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. The OSTEON is an 70% TCP Synthetic Bone Graft material with 30% Hydroxyapatite coated on it. The powder contains particles of 500-1000 microns.

#### **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 OSTEON, from Dentium company, Korea, 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. The OSTEON is an 70% TCP Synthetic Bone Graft material with 30% Hydroxyapatite coated on it. The powder contains particles of 500-1000 microns.

#### **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**

Nima Nadaf pour

##### **Street address**

Tehran, Pasdaran Street, Ninth Neyestan Avenue

##### **City**

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##### **Postal code**

1946853314

##### **Phone**

+98 21 2256 4571

##### **Email**

zm.mosalmani1993@gmail.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Arash Azizi

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Tehran, Pasdaran Street, Ninth Neyestan Avenue

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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**

Nima Nadaf Pour

##### **Position**

Periodontics professor

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Dentistry  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Zahra Mosalmani  
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zm.mosalmani1993@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, case group) and long-term (4 months, control group) Application of synthetic HA /  $\beta$ -TCP on histopathology of bone formation following tooth extraction in patients referring to the 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 the results

### To whom data/document is available

All people who need data

### Under which criteria data/document could be used

Analyzes that do not damage the outcome of our data analysis are allowed.

### 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