

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effects of BonePlus+C and Bio-Oss in socket preservation after extraction

#### Protocol summary

##### Study aim

With this study, it is aimed to determine which of the xenografts: Bio-Oss and BonePlus+C, are more successful in socket preservation after extraction.

##### Design

randomized clinical trial with control group, parallel group, double blinded

##### Settings and conduct

This split mouth designed randomized clinical trial is conducted on patients in need of at least two extractions in the same jaw. Patients refer to the Oral and Maxillofacial department of dental branch of Islamic Azad University of Tehran, and have the indication of delayed implant placement. Extractions are done by a surgeon and dental sockets are randomly divided into control (Bio-Oss) and examine (BonePlus+C) groups. sockets are filled with these bio materials. After four months, patients are recalled and healing is assessed via biopsy of the grafted sites and histomorphometric analysis.

##### Participants/Inclusion and exclusion criteria

Patients in need of at least two extractions in the same jaw with the indication of delayed implant placement. Patients have a good overall health and the exclusion criteria is as followed: systemic and metabolic diseases, periapical lesion, acute infection at the site of surgery, smoking more than 10 cigarettes per day.

##### Intervention groups

In order to improve the healing of bone defects after extraction, alveplae sockets of each patient are randomly divided into control (Bio-Oss) and examine (BonePlus+C) groups; and the sockets are filled with these bio-materials.

##### Main outcome variables

number of pixels of newly formed bone; number of pixels of remained bio-material

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180619040159N1**  
Registration date: **2018-07-07, 1397/04/16**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-07, 1397/04/16**

Update count: **0**

##### Registration date

2018-07-07, 1397/04/16

##### Registrant information

##### Name

Farnaz Keyhanlou

##### Name of organization / entity

Tehran Dental Branch of Islamic Azad University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2239 4855

##### Email address

f\_sarkarat@dentaliau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-05, 1397/03/15

##### Expected recruitment end date

2018-08-11, 1397/05/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effects of BonePlus+C and Bio-Oss in socket preservation after extraction

**Public title**

BonePlus+C in socket preservation

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with a good overall health in need of at least two extractions in the same jaw with the indication of delayed implant placement

**Exclusion criteria:**

Patients with systemic or metabolic diseases Existing periapical lesion Presence of acute infection at the site of surgery Smoking more than ten cigarettes per day

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **5**

More than 1 sample in each individual

Number of samples in each individual: **2**

Alveolar socket after extraction

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The extraction sockets in each patient were randomly divided into control and examine groups by Excel software. Date were given to the function of "Random" in this software, and the output contained the information on the type of material that should be placed in each extraction socket.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients are blind towards the control and examine groups applied to their sockets. They are not aware of the type of material that is placed in each extraction socket. In addition, pathologist of the study is also blind towards the type of samples. The samples sent to the pathologist only contain a given number, and no further information about the type of material or the patient; and only the surgeon is aware of this information.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Dental branch of Islamic Azad University of Tehran

**Street address**

No. 4, 10th Neyestan, Pasdaran Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

19585175

**Approval date**

2016-12-20, 1395/09/30

**Ethics committee reference number**

IR.IAU.DENTAL.REC.1397,1

**Health conditions studied****1****Description of health condition studied**

Bony defects of alveolar socket after extraction

**ICD-10 code**

M84.8

**ICD-10 code description**

Other disorders of continuity of bone

**Primary outcomes****1****Description**

number of pixels of newly formed bone

**Timepoint**

4 months after the first surgery

**Method of measurement**

Histomorphometric analysis

**2****Description**

number of pixels of remained bio-material

**Timepoint**

4 months after the first surgery

**Method of measurement**

Histomorphometric analysis

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: placement of Bio-Oss bio-material in the extraction socket

**Category**

Treatment - Other

## 2

### Description

Intervention group: placement of BonePlus+C bio-material in the extraction socket

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

بخش جراحی دهان و فک و صورت دانشگاه آزاد اسلامی تهران

##### Full name of responsible person

فرزین سرکارات

##### Street address

No. 4, 10th Neyestan, Pasdaran Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

19585175

##### Phone

+98 21 2258 0933

##### Email

f\_sarkarat@dentaliau.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Dental Branch of Islamic Azad University of Tehran

##### Full name of responsible person

Farzin Sarkarat

##### Street address

No. 4, 10th Neyestan, Pasdaran Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

19585175

##### Phone

+98 21 2258 0933

##### Email

f\_sarkarat@dentaliau.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Dental Branch of Islamic Azad University of Tehran

##### 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

Dental Branch of Islamic Azad University of Tehran

#### Full name of responsible person

Farzin Sarkarat

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

#### Street address

No. 4, 10th Neyestan, Pasdaran Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

19585175

#### Phone

+98 21 2258 0933

#### Email

f\_sarkarat@dentaliau.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Dental Branch of Islamic Azad University of Tehran

#### Full name of responsible person

Farzin Sarkarat

#### Position

Associate Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

#### Street address

No. 4, 10th Neyestan, Pasdaran Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

19585175

#### Phone

+98 21 2258 0933

#### Email

f\_sarkarat@dentaliau.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Dental Branch of Islamic Azad University of Tehran

**Full name of responsible person**

Farnaz Keyhanlou

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

No. 4, 10th Neyestan, Pasdaran Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

19585175

**Phone**

+98 21 2258 0933

**Email**

farnazz.kay@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information.

**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