

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effects of BonePlus+B 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+B, are more successful in socket preservation after extraction.

Design

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

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+B) 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, alveolae sockets of each patient are randomly divided into control (Bio-Oss) and examine (BonePlus+B) 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: **IRCT20180619040159N2**

Registration date: **2018-07-13, 1397/04/22**

Registration timing: **retrospective**

Last update: **2018-07-13, 1397/04/22**

Update count: **0**

Registration date

2018-07-13, 1397/04/22

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

2018-07-11, 1397/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

BonePlus+B 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 in 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 .

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are blind towards the control and examine groups applied to their sockets. In addition, pathologist of the study is also blind towards the type of samples.

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.1395.2

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+B bio-material in the extraction socket

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and Maxillo-facial Department 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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental Branch of Islamic Azad University of Tehran

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

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

دانشکده دندانپزشکی دانشگاه آزاد اسلامی

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