Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, alveplae 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

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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.

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Tehran

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19585175

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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.

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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
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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
Specialist

Other areas of specialty/work
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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
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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