

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim

Comparison of short-term effects (3 months, case group) and long-term (4 months, control group) of HA/ β -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 Trephine 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/ β -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/β-TCP

Public title
Effect of HA/β-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/β-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

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Tehran, Pasdaran Street, Ninth Neyestan Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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 / β -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