

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Assessment of histological outcomes of post extraction socket preservation using xenograft bone substitute

Protocol summary

Study aim

The main purpose of this study was to evaluate the inflammatory reaction and amount of new bone formed in the socket ridge after bone grafting.

Design

Double-blind clinical trial will performed on 10 patient with at least one extracted tooth socket. All of the sockets will be filled with Bone+B xenograft biomaterials.

Settings and conduct

This pilot study is performed at shahid beheshti dental school. After receiving informed consent, conservative tooth extraction will be done under local anesthesia. The tooth socket will be filled with the Bone + B biomaterial up to the bone level, covered with collagen sponge and protected with resorbable cross sutures. After 6 months, tissue samples will be taken with trephine bur and dental implants will be inserted.

Participants/Inclusion and exclusion criteria

Age over 18 years Good general health Absence of any infection or periapical lesions Absence of any uncontrolled systemic disease disrupts the healing process (uncontrolled diabetes, ...)

Intervention groups

In this study, Bone + B bone xenograft is used as single biomaterials will be used. there is no control group.

Main outcome variables

degree of tissue inflammation amount of foreign body reaction proportion of blood vessels proportion of newly formed bone and proportion of graft remnants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201209049656N1**

Registration date: **2021-02-11, 1399/11/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-11, 1399/11/23**

Update count: **0**

Registration date

2021-02-11, 1399/11/23

Registrant information

Name

Reza Amid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8803 2208

Email address

reza_amid@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-09, 1399/10/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of histological outcomes of post extraction socket preservation using xenograft bone substitute

Public title

Alveolar ridge preservation with graft material

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

> 18 years old good systemic health minimum one tooth

irrational to restoration informed consent

Exclusion criteria:

local infection/ periapical defect uncontrolled diabetes
smoking alcohol abuse

Age

From **18 years** old

Gender

Both

Phase

1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **1**
extracted tooth socket

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

a blinded examiner a blinded statistician

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti university of
medical sciences

Street address

Shahid Beheshti University of Medical Sciences, Evin,
Daneshjoo Blvd., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2020-11-24, 1399/09/04

Ethics committee reference number

IR.SBMU.DRC.REC.1399.054

Health conditions studied

1

Description of health condition studied

Candidate patients to extract teeth and receive implants

ICD-10 code

K08.2

ICD-10 code description

Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description

Histological examinations to determine bone integrity,
amount of newly formed bone tissue, amount of
biomaterial residue, evaluation of immune stimulation
reactions, examination of connective tissue and
observation of fibrosis

Timepoint

The amount of bone in the socket is examined 6 months
later.

Method of measurement

Histologic evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: fresh tooth sockets filled with
xenograft biomaterials

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti dental school

Full name of responsible person

Reza Amid

Street address

Shahid beheshti dental school, Daneshjoo Blv, Evin

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2242 7752

Fax

+98 21 2242 7753

Email

Amidperio@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice- Chancellor in Research Affairs

Street address

Shahid beheshti university of medical sciences, Evin

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2217 5351

Fax

+98 21 2240 3194

Email

info@novateb.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Amid

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Daneshju Blvd, Evin

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2217 5351

Email

rezaa_amid@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Amid

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Daneshjoo Blvd, Evin, Shahid Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 8802 0238

Email

reza_amid@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Amid

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Daneshjoo Blvd, Evin, Shahid Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2242 7752

Email

reza_amid@yahoo.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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

6 months after the results are published

From where data/document is obtainable

Dr. Reza Amid, Shahid Beheshti Dental University

What processes are involved for a request to access data/document

Fill in the application form and send it to Shahid Beheshti Dental University

Comments