

# 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