

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### A comparison of osteobiol gen\_os with normal healing extraction socket in quality and quantity of bone formation for implant placement in partial edentulous patients

#### Protocol summary

##### Summary

The aim of this research is to evaluate a kind of bone material xenograft (ostel biol gen\_os) in socket regeneration. Patients need to extract two teeth in two contra-lateral quadrant. They have not systemic disease like Diabetes, Autoimmune disorder, viral and bacterial infection. They are not smokers and their cooperation is good. This is a randomized clinical trial study. 12 cases (6 test and 6 control in 6 patients) were selected. After tooth removal the grafting material put in the socket. 3 to 4 month later during implant placement, the specimen from both sites are sent for histologic and histomorphometric evaluation.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT201202018898N1**  
Registration date: **2012-07-25, 1391/05/04**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-07-25, 1391/05/04

##### Registrant information

###### Name

Mojgan Paknejad

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8801 5801

##### Email address

mpaknejad@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Dental Research Center, Tehran University of Medical Science

##### Expected recruitment start date

2012-06-21, 1391/04/01

##### Expected recruitment end date

2012-08-22, 1391/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparison of osteobiol gen\_os with normal healing extraction socket in quality and quantity of bone formation for implant placement in partial edentulous patients

##### Public title

effect of osteobiol gen\_os in healin process of socket

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: presence of two hopeless teeth in two quadrant of the jaw exclusion criteria: systemic disease such as diabetes, autoimmune disorder, viral and bacterial infection; smoker; patients with poor compliance and poor oral hygiene ; metabolic disorder that affected bone

##### Age

From **30 years** old to **65 years** old

##### Gender

Both

**Phase**  
N/A

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 12

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Faculty of Dentistry, Tehran University of Medical Science

##### Street address

Faculty of Dentistry, Tehran University of Medical Science, Karegar Shomali St, Hakim Hwy, Tehran, IRAN

##### City

Tehran

##### Postal code

55991\_14399

##### Approval date

2006-12-23, 1385/10/02

##### Ethics committee reference number

8601694798

## Health conditions studied

### 1

#### Description of health condition studied

extraction of teeth due to periodontitis

#### ICD-10 code

K05, K08

#### ICD-10 code description

k 05:Gingivitis and periodontal diseases, k 08:Other disorders of teeth and supporting structures

## Primary outcomes

### 1

#### Description

percentage of regenerative bone

#### Timepoint

4 month after extraction

#### Method of measurement

estimation of bone filled surface with photoshop software

### 2

#### Description

type of regenerating bone

#### Timepoint

4 month after extraction

#### Method of measurement

light microscope

### 3

#### Description

percentage fo remaining material

#### Timepoint

4 month after extraction

#### Method of measurement

evaluation of material filled surface with photoshop software

## Secondary outcomes

### 1

#### Description

bone vitality

#### Timepoint

4 month after extraction

#### Method of measurement

light microscope

### 2

#### Description

foregin body reaction

#### Timepoint

4 month after extraction

#### Method of measurement

light microscope

### 3

#### Description

inflammation

#### Timepoint

4 month after extraction

#### Method of measurement

number of inflammatory cells in high power field

## Intervention groups

### 1

#### Description

putting bone graft in socket and sampling during implamentation surgery

#### Category

Treatment - Surgery

## 2

### Description

control group:no intervention after extraction and sampling during implamentation surgery

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Periodontology Center, Faculty of Dentistry, Tehran University of Medical Science

##### Full name of responsible person

Mojgan Paknejad

##### Street address

Faculty of Dentistry, Tehran University of Medical Science, Karegar Shomali St, Hakim Hwy, Tehran, IRAN

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Dental Research Center, Tehran University of Medical Science

##### Full name of responsible person

Elahe Alamdar

##### Street address

Tehran University of Medical Science, Ghods St, Enghelab Ave, Tehran, Iran

##### City

Tehran

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Dental Research Center, Tehran University of Medical Science

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Faculty of Dentistry, Tehran University of Medical Science

#### Full name of responsible person

Mohadeseh Heidari

#### Position

Resident of Periodontology

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Faculty of Dentistry, Tehran University of Medical Science

#### Full name of responsible person

Mojgan Paknejad

#### Position

Profesor assistant, Peridontologist

#### Other areas of specialty/work

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#### Web page address

## Person responsible for updating data

### Contact

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Faculty of Dentistry, Tehran University of Medical Science

#### Full name of responsible person

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#### Other areas of specialty/work

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*