

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Assessment of Pamidronate effect on bone mineral density of kidney transplant patients in comparison with Alendronate in the first 6 month after transplantation

#### Protocol summary

##### Summary

The objective of this study was to investigate the effect of Bisphosphonate on osteoporosis in patients undergone kidney transplantation. 40 candidates of kidney transplantation, aged more than 20 years old, with low bone mineral density (T-Score < -2) in spine, total femur, or femoral neck, regardless the cause of end stage renal disease, were randomly assigned to receive Pamidronate or Alendronate. Pamidronate was administered as 90 mg infusions at the beginning and after three months. Alendronate, 70 mg orally, was administrated weekly for 6 months. Drug administration began in the third week for both groups. Both groups received standard treatment protocol including Prednisolone, Cyclosporine, and Mycophenolate Mofetil. Bone mineral density was measured via dual-energy x-ray absorptiometry (DXA) by a trained technician with a single instrument at the beginning and 6 months later. Plasma level of Parathormone hormone (PTH) was assessed at the beginning and at the end of study. Plasma level of calcium, phosphorus, alkaline phosphatase, blood urea, creatinine, and cyclosporine were measured monthly.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138804162109N1**  
Registration date: **2010-03-20, 1388/12/29**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-03-20, 1388/12/29

##### Registrant information

##### Name

Bitra Omidvar

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1445 7205

##### Email address

bita.omidvar@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapur University of Medical Science

##### Expected recruitment start date

2008-10-05, 1387/07/14

##### Expected recruitment end date

2009-01-04, 1387/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of Pamidronate effect on bone mineral density of kidney transplant patients in comparison with Alendronate in the first 6 month after transplantation

##### Public title

Effect of bisphosphonate on osteoporosis in kidney transplant patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Kidney transplantation candidates, aged above 20 with low bone mineral density (T-Score <

-2) in spine or total femur or femoral neck. Exclusion criteria: Inability to stay in upright position for 30 minute, History of hypersensitivity reaction, Hyperparathyroidism, Hyperthyroidism, Hypocalcemia, Hypercalcemia, GFR < 35 ml/min or creatinine > 3 mg/dL, Active peptic ulcer disease, Jaw avascular necrosis, Uveitis, History of fracture during 2 years prior to the study, Achalasia, or delayed esophagus emptying

#### Age

From **20 years** old to **70 years** old

#### Gender

Both

#### Phase

4

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

##### Street address

P.O.box: 61537-15794, Ahvaz Jundishapur University of Medical Sciences, Shahr-e-daneshgahi

##### City

Ahvaz

##### Postal code

61537-15794

#### Approval date

2008-09-05, 1387/06/15

#### Ethics committee reference number

820/2973/پ

## Health conditions studied

### 1

#### Description of health condition studied

kidney transplant patients with low bone mineral density

#### ICD-10 code

Z94.0

#### ICD-10 code description

Kidney transplant status

## Primary outcomes

### 1

#### Description

Bone mineral density

#### Timepoint

6 months

#### Method of measurement

Dual-energy X-ray absorptiometry

## Secondary outcomes

### 1

#### Description

Glomerular Filtration Rate

#### Timepoint

Every month

#### Method of measurement

Cockcroft-Gault

### 2

#### Description

Serum Intact Parathormone hormone (iPTH)

#### Timepoint

Every 6 months

#### Method of measurement

Radioimmunoassay

### 3

#### Description

Blood level of Cyclosporine

#### Timepoint

Every month

#### Method of measurement

Radioimmunoassay

## Intervention groups

### 1

#### Description

Pamidronate 90 mg infused in the third week of transplant and third month after the first dose

#### Category

Treatment - Drugs

### 2

#### Description

Alendronate 70 mg orally administered weekly for 6 months

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Golestan Hospital

**Full name of responsible person**

Bitra Omidvar

**Street address**

**City**

Ahvaz

**Street address**

Golestan Hospital, Internal Medicine Department office

**City**

Ahvaz

**Postal code**

**Phone**

+98 61 1374 3013

**Fax**

**Email**

arashrad57@yahoo.com

**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr.Bitra Omidvar

**Street address**

Golestan hospital, Internal Medicine department office

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz Jundishapur University of Medical Sciences

**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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Seyed Javad Shariat Nabavi

**Position**

Internal Medicine Resident

**Other areas of specialty/work**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr.Bitra Omidvar

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Golestan Hospital, Internal Medicine Department

**City**

Ahvaz

**Postal code**

**Phone**

+98 61 1374 3013

**Fax**

**Email**

bita.omidvar@ajums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

## 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*