Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Bita Omidvar
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Ahvaz Jundishapur University of Medical Sciences
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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 druring 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
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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 absoptiometry

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
Pmidronate 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
Bita Omidvar
Street address
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr.Bita Omidvar
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Golestan hospital, Internal Medicine department office
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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
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
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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