

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effect of Alendronate on Bone Densitometry in Osteoporetic Chronic Kidney Disease Stage 3a-3b

#### Protocol summary

##### Study aim

Effect of Alendronate on Bone Densitometry in Osteoporetic Chronic Kidney Disease Stage 3a-3b

##### Design

Clinical Trial with Control Group, was Double Blinded Through Patients', Assessor and Analyzer Blinding on 82 Osteoporosis Patients with Chronic Kidney Disease, 41 in Control Group and 41 in Intervention Group by Final Allocation Method.

##### Settings and conduct

The study will be carried out in Nephrology section of Imam Khomeini Hospital of Ahvaz. Blinding is done in the way that in order to Reduce the likelihood of Bias in information, Patients, Assessor, Analyzer, the Results, the Type of Treatment Assigned to each Patient and the Groups Including Patients will be Kept in Secret

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Osteoporotic Patients over 18 years of Age with Chronic Kidney Disease stage 3a-3b Exclusion Criteria: Patients who Suffer From Hyperparathyroidism, Hypoparathyroidism or Normal Densitometry at The same Time are Excluded.

##### Intervention groups

Osteoporotic Patients over 18 Years of Age with Chronic Kidney Disease of Stage 3a-3b are Divided into the Intervention and Control Groups by Random Final Allocation Method using a Six-Block Test. Patients in the Main Group Receive Alendronate 70 mg Per Week in a Single dose Before Breakfast for 6 months. Patients in the Control Group also Receive Placebo once a Week in a Single dose, Before Breakfast and for 6 Months. The placebo in Terms of its Appearance, Size, Taste and Color is Similar to That of The Original Group.

##### Main outcome variables

Bone Density

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180506039549N1**

Registration date: **2018-10-22, 1397/07/30**

Registration timing: **retrospective**

Last update: **2018-10-22, 1397/07/30**

Update count: **0**

##### Registration date

2018-10-22, 1397/07/30

##### Registrant information

###### Name

benyamin masmou

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 5283 0763

###### Email address

masmou.b@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-06, 1397/05/15

##### Expected recruitment end date

2018-09-11, 1397/06/20

##### Actual recruitment start date

2017-10-23, 1396/08/01

##### Actual recruitment end date

2017-12-16, 1396/09/25

##### Trial completion date

empty

##### Scientific title

Effect of Alendronate on Bone Densitometry in Osteoporetic Chronic Kidney Disease Stage 3a-3b

**Public title**

Effect of Alendronate in Patents with Osteoporosis and Chronic Kidney Disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Osteoporotic Patients with Chronic Kidney Disease  
Patients over 18 years of Age

**Exclusion criteria:**

Patients with hyperparathyroidism Patients with hypoparathyroidism Patients with normal Densitometry

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **82**

Actual sample size reached: **82**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block Randomization With Using Six Blocks, One Group Including Intervention and another Group is Placebo, and Patients Selected Randomly According to The Blocks.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

To reduce the risk of bias, patient and assessor and statistician were blinded to know the type of treatment assigned to each person and that which patient was in which group

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Golestan St , Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Approval date**

2018-08-04, 1397/05/13

**Ethics committee reference number**

IR.AJUMS.REC.1397.369

**Health conditions studied****1****Description of health condition studied**

Chronic Kidney Disease Stage 3a-3b

**ICD-10 code**

N18.3

**ICD-10 code description**

Chronic kidney disease, stage 3 (moderate)

**Primary outcomes****1****Description**

Bone density in patients with Chronic Kidney Disease Stage 3a-3b

**Timepoint**

Before and 6 months after study

**Method of measurement**

Densitometry

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Alendronate 70mg Tablet Produced by Abidi Company Will Orally be Administered to This Group once a Week Before Meals, with a Glass of Water for 6 Months.

**Category**

Treatment - Drugs

**2****Description**

Control group: Placebo is Administered to This Group in the Form of Pills with The same dose and Duration as The Intervention Group. The Placebo will be Produced at the Faculty of Pharmacy, Jundishapur University of Medical Sciences, Ahvaz, and its Appearance, Size, Taste and Color are similar to those of the main Group

**Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Nephrology ward of Emam Khomeini hospital of Ahwaz

**Full name of responsible person**

Shokouh Shayanpour

**Street address**

Azadegan Ave

**City**

Ahwaz

**Province**

Khouzestan

**Postal code**

6193673111

**Phone**

+98 61 3222 2922

**Email**

shayanpour-sh@ajums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahwaz University of Medical Sciences

**Full name of responsible person**

Dr. Majid Karandish

**Street address**

Golestan St , Ahwaz

**City**

Ahwaz

**Province**

Khouzestan

**Postal code**

61357-12794

**Phone**

+98 61 3333 7077

**Email**

info@ajums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahwaz 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**

Ahwaz University of Medical Sciences

**Full name of responsible person**

Shokouh Shayanpour

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Golestan St , Ahwaz

**City**

Ahwaz

**Province**

Khouzestan

**Postal code**

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**Email**

shayanpor.sh@ajums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahwaz University of Medical Sciences

**Full name of responsible person**

Shokouh Shayanpour

**Position**

Assistant Professor of Nephrology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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**Province**

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

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**City**

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**Province**

Khouzestan

**Postal code**

61357-12794

**Phone**

+98 61 3333 7077

**Email**

shayanpour.sh@ajums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available