

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Assessment of oral Nicotinamide effects on serum phosphorus in hemodialysis patients in Imam Khomeini and Golestan hospitals of Ahvaz in 2010

Protocol summary

Summary

This was a randomized, double-blind study designed for determination of the effect of oral nicotinamide on serum phosphorus in hemodialysis patients. The study population was hemodialysis patients attending Imam Khomeini and Golestan hospitals of Ahvaz. Forty-six eligible hemodialysis patients with age above 18 and serum phosphorus ≥ 5 mg/dl and good cooperation who weren't affected by liver or active peptic disease were randomized to two groups, Nicotinamide (treatment group) and placebo, and were studied for two months. Oral Nicotinamide is administered to treatment group for 8 weeks, 500 mg daily (in two divided doses) for first 4 weeks and 1000 mg daily (in two divided doses) for the second four weeks. Since the primary outcome is the change in serum phosphorus, the fasting serum phosphorus was measured at the beginning, at week 5 and week 9. Also serum lipids and iPTH were measured before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809172817N1**

Registration date: **2010-02-16, 1388/11/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-16, 1388/11/27

Registrant information

Name

Azita Zafar Mohtashami

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 1330

Email address

azmohtashami@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2009-11-22, 1388/09/01

Expected recruitment end date

2010-01-15, 1388/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of oral Nicotinamide effects on serum phosphorus in hemodialysis patients in Imam Khomeini and Golestan hospitals of Ahvaz in 2010

Public title

Assessment of oral Nicotinamide effects on serum phosphorus in hemodialysis patients in Imam Khomeini and Golestan hospitals of Ahvaz in 2010

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age > 18 years old, hemodialysis for more than 3 months, constant use of phosphate binder in recent two weeks, serum phosphorus ≥ 5 Exclusion Criteria: liver disease or significant disturbance in liver

function tests, active peptic ulcer, poor cooperation, severe diarrhea

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz Jondishapour University of Medical Sciences

Street address

Golestan, Campus of the University

City

Ahvaz

Postal code**Approval date**

2010-01-17, 1388/10/27

Ethics committee reference number

8/20/4101/پ

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

Hemodialysis patients (ESRD)

ICD-10 code

N18.0

ICD-10 code description

End-stage renal disease

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

Serum phosphorus

Timepoint

week 0, 5 and 9 of the study

Method of measurement

serum phosphorus measurement by biochemistry autoanalyser

Secondary outcomes**1****Description**

Serum iPTH

Timepoint

before and after the intervention

Method of measurement

Chemiluminescence iPTH measurement

2**Description**

Serum lipids

Timepoint

before and after the intervention

Method of measurement

serum biochemistry by autoanalyser

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

Placebo administered as tablets to control group for two months.

Category

Placebo

2**Description**

Oral Nicotinamide is administered to intervention group for 8 weeks: 500 mg daily in two doses for first 4 weeks and 1000 mg daily in two doses for the second four weeks.

Category

empty

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Miss Khodashenas, Mrs Shehni

Street address

Imam Khomeini Hospital of Ahvaz

City

Ahvaz

2

Recruitment center

Name of recruitment center

Golestan Hospital of Ahvaz

Full name of responsible person

Mrs Kadkhodazadeh

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Miss Jaderi

Street address

Golestan boulevard, Campus of the university

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jondishapour 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

Golestan Hospital - Ahvaz University of Medical sciences

Full name of responsible person

Dr. Azita Zafar Mohtashami

Position

Fellowship of Nephrology

Other areas of specialty/work

Street address

Golestan Hospital

City

Ahvaz

Postal code

Phone

+98 61 1374 3013

Fax

+98 61 1374 3013

Email

azmohtashami@ajums.ac.ir

azmohtashami@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Heshmatolah Shahbazian

Position

Associate professor - Director of internal medicine

Other areas of specialty/work

Street address

Golestan Hospital

City

Ahvaz

Postal code

Phone

+98 61 1374 3013

Fax

+98 61 1374 3013

Email

shahbazian_he@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Golestan Hospital - Ahvaz University of Medical Sciences

Full name of responsible person

Azita Zafar Mohtashami

Position

Fellowship of Nephrology

Other areas of specialty/work

Street address

Golestan Hospital - Nephrology ward

City

Ahvaz

Postal code

Phone

+98 61 1374 3013

Fax

+98 61 1374 3013

Email

azmohtashami@ajums.ac.ir, azmohtashami@yahoo.com

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