Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of nicotinic acid on hyperphosphatemia in dialysis patients of valiasr-Arak center

Protocol summary

Summary

The aim of this study is evaluation of the effects of nicotinic acid on hyperphosphatemia in dialysis patients of Valiasr-Arak center. Hyperphosphatemia is one of the most common metabolic disorders in end-stage renal disease patients that is independent risk factor for cardiovascular disease. It has been shwon that correction of Hyperphosphatemia decreases left ventricular hypertrophy. Bone fracture, chronic arthralgia , diffuse itching, fatigue, generalized , anxiety are also other effects of Hyperphosphatemia that affect quality of life. Low dietary intake of phosphate is not enough to control Hyperphosphatemia and needs extra medication to reduce dietary phosphate absorption. Nicotinic acid or vit B3 has been used as a drug for Hyperphosphatemia. Currently the most common indication for niacin or nicotinic acid is decreasing triglyceride and increasing HDL. The most important side effect of niacin is vasodilation and hot flush, that is due to prostaglandin production and is controllable with aspirin. GI discomfort such as cramps and diarrhea are other niacin side effects. At 2004, nicotinic acid was used to reduce serum phosphorous. Nicotinic acid inhibits phosphorous handling and intestinal absorption. Now a days, many clinical trials established effects of nicotinic acid in dialysis patients to control Hyperphosphatemia. This clinical trial is a prospective study with case and control group in hemodialysis patients in Valiasr-Arak center to evaluate effects of niacin on serum phosphorous. After obtaining informed consent, patients will be randomly classified in two groups. Group I will receive nicotinic acid and group II will receive placebo. Nicotinic acid will be started as 400 mg/day, patients will be controlled for nicotinic acid's side effects such as GI problems and thrombocytopenia. Calcium & phosphorous will be checked every other week. If serum calcium and phosphorous is greater than 4 mg/day, nicotinic acid will be increased to 600 mg/day (200 mg additional). If phosphorous is lesser than 3.5 mg/day, nicotinic acid will be reduced to 200 mg/day. If serum phosphorous is between 3.5 – 4 mg/day, it will remain unchanged. Nicotinic acid will continue till 8 weeks. Two weeks later, case and control groups will change place with regard to the reception of nicotinic acid and placebo. Now group II will receive nicotinic acid for 8 weeks. In addition to calcium and phosphorous, CBC, PTH, lipid profile will be checked at 0-8-18 weeks. This way, we will evaluate nicotinic acid effects on serum phosphorous in dialysis patients. During the study, dialysis protocol of patients will remain unchanged and dialysis efficacy will be evaluated by BUN & creatinine before and after hemodialysis. Binding drugs to phosphorous and Vit D will be continued as before. Inclusion criteria: Age > 18&<90 years, sign satisfaction, serum phosphorous: 5-7 mg/day, unchanged treatment protocol, (calcium components and Vit D) during last two weeks, unchanged dialysis protocol. Exclusion criteria: pregnancy, known liver disease, active peptic ulcer, carbamazepine use, drug intolerance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812153492N1**
Registration date: **2010-02-20, 1388/12/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-02-20, 1388/12/01

Registrant information

Name

Mahnaz Edalat-Nejad

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1417 3630

Email address

mahedalat@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Science

Expected recruitment start date

2010-02-20, 1388/12/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of nicotinic acid on hyperphosphatemia in dialysis patients of valiasr-Arak center

Public title

The effects of nicotinic acid on hyperphosphatemia in dialysis patients of valiasr-Arak center

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Age > 18&<90 years, sign satisfaction, serum phosphorous: 5-7 mg/day , unchanged treatment protocol , (calcium components and Vit D) during last two weeks , unchanged dialysis protocol. Exclusion criteria: pregnancy, known liver disease, active peptic ulcer, carbamazepine use, drug intolerance.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak university of medical science

Street address

Alamolhoda Avenu

City

Arak

Postal code

3819693345

Approval date

2009-12-22, 1388/10/01

Ethics committee reference number

6-67-88

Health conditions studied

1

Description of health condition studied

Hyperphosphatemia

ICD-10 code

E83.3

ICD-10 code description

disorder of phosphorus metabolism

Primary outcomes

1

Description

Serum phosphate level

Timepoint

Twice a weeks for 4 months

Method of measurement

by pars azmon kit in Valiasr Hospital

Secondary outcomes

1

Description

HDL Level

Timepoint

0-2-4 month

Method of measurement

Pars Azmoon kit in Valiasr Hospital Lab

2

Description

Serum calcium level

Timepoint

Twice a week for 4 mounths

Method of measurement
by pars kit in valiasr hospital

Intervention groups

1

Description
Placebo
Category
Placebo

2

Description
Intervention group (Group I) will receive nicotinic acid and group II will receive placebo. Nicotinic acid will be started as 400 mg/day, patients will be controlled for nicotinic acid's side effects such as GI problems and thrombocytopenia. Calcium & phosphorous will be checked every other week. If serum calcium and phosphorous is greater than 4 mg/day, nicotinic acid will be increased to 600 mg/day (200 mg additional). If phosphorous is lesser than 3.5 mg/day, nicotinic acid will be reduced to 200 mg/day. If serum phosphorous is between 3.5 – 4 mg/day, it will remain unchanged. Nicotinic acid will continue till 8 weeks. Two weeks later, case and control groups will change place with regard to the reception of nicotinic acid and placebo. Now group II will receive nicotinic acid for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hemodialysis Center
Full name of responsible person
Fatemeh Zameni
Street address
Valiasr Hospital
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Depuity of education & research of Arak university of Medical science
Full name of responsible person
Saeed Changizi Ashtiani
Street address
Alamolhoda Avenu
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Depuity of education & research of Arak 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
Arak University of medical science
Full name of responsible person
Fatemeh Zameni
Position
Assistant of Internal Medical Science
Other areas of specialty/work
Street address
Alamalhoda Avenue
City
Arak
Postal code
3819693345
Phone
+98 86 1312 1394
Fax
Email
fzameni-malek@arakmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak medical science university
Full name of responsible person
Mahnaz Edalat-Nejad
Position
Adult nephrology
Other areas of specialty/work
Street address
Amir-Almomenin Hospital , Sardasht, Arak
City
Arak
Postal code
Phone
+98 86 1417 3645
Fax
+98 86 1417 3630

Email
mahedalat@arakmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arak Medical University
Full name of responsible person
Mahnaz Edalatnejad
Position
Subespecialist In Adult Nephrology
Other areas of specialty/work
Street address
Sardasht-Amiralmomenin Hospital
City
Arak
Postal code
Phone
+98 86 1417 3645
Fax
+98 86 1417 3630
Email
mahedalat@arakmu.ac.ir
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