# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

05 Jul 2026

## The effects of Nicotinic acid on serum phosphorus, PTH and lipid profile in dialysis patients .

## Protocol summary


**Summary**

The aim of this study is evaluation of the effects of nicotinic acid on hyperphosphatemia, PTH and lipid profile in dialysis patients of Imam Hossein hospital of Shahroud. Hyperphosphatemia is one of the most common metabolic disorders in end-stage renal disease patients that is independent that causes change of PTH. Bone fracture, chronic arthralgia , diffuse itching, fatigue, generalized , anxiety are sever changing of lipid profile of Hyperphosphatemia that affect quality of life. Low dietary intake of phosphate is not enough to control Hyperphosphatemia, PTH and hyperlipidemia and needs extra medication to reduce dietary phosphate absorption. Currently the most common indication for niacin or nicotinic acid is control of hyperlipidemia. The most important side effect of niacin is vasodilation and hot flush, that is due to prostaglandin production and is controllable with aspirin. This clinical trial is a prospective study with case and control group in hemodialysis patients in Shahroud to evaluate effects of niacin on serum phosphorous, PTH and lipid profile. After obtaining informed consent, patients will be randomly classified in two groups. Group I will receive nicotinic acid and group II will receive placebo. Inclusion criteria: Age > 15 &<70 years; sign satisfaction; serum phosphorous: 5-7 mg/dl; PTH level > 550 ug/ml; TG >350mg/ml; LDL>150mg/ml and HDL<25 mg/ml; 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 and not satisfaction of patients. Nicotinic acid will be started as 200 mg/day, patients will be controlled for nicotinic acid's side effects such as GI problems and thrombocytopenia. Calcium & phosphorous will be checked every 2 weeks and per month 200 mg/day nicotinic acid will be increased to 600 mg/day (200 mg additional per month). If phosphorous is lesser than 3.5 mg/day, nicotinic acid will be reduced to 200 mg/day. Nicotinic acid will continue till 12 weeks. Then control group, placebo was used similar case group( 200 mg/day to 600 mg/day in third months) In addition to calcium and phosphorous, PTH will be checked at 0-4-8 and 12 weeks and lipid profile will be checked at 0 and 12 weeks . 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.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201402212954N4**
Registration date: **2014-04-12, 1393/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2014-04-12, 1393/01/23

**Registrant information**


**Name**
Mohammad Bagher Sohrabi
**Name of organization / entity**
Shahroud University of Medical Ssciences and Health
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**Recruitment status**

**Recruitment complete**

**Funding source**

Investigator

**Expected recruitment start date**
2014-03-06, 1392/12/15
**Expected recruitment end date**
2014-09-06, 1393/06/15
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effects of Nicotinic acid on serum phosphorus, PTH and lipid profile in dialysis patients .

**Public title**
The effects of Nicotinic acid on serum phosphorus, PTH and lipid profile in dialysis patients .
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: Age > 15 &<70 years; sign satisfaction; serum phosphorous: 5-7 mg/dl; PTH level > 550 ug/ml; TG >350mg/ml; LDL>150mg/ml and HDL<25 mg/ml; 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 and not satisfaction of patients.
**Age**
From **15 years** old to **70 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **120**
**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 Shahroud University of Medical science
**Street address**
Vice chancellor for research, Shahroud University of Medical Science,7th Tir squer
**City**
Shahroud
**Postal code**
3616611151
**Approval date**
2013-10-07, 1392/07/15
**Ethics committee reference number**
930/06

## Health conditions studied

### 1

**Description of health condition studied**
Hyperphosphatemi
**ICD-10 code**
E83.3
**ICD-10 code description**
Disorder of phosphorus metabolism

### 2

**Description of health condition studied**
Hyperlipidaemia
**ICD-10 code**
E78.2
**ICD-10 code description**
Mixed hyperlipidaemia

### 3

**Description of health condition studied**
Hyperparathyroidism
**ICD-10 code**
M83.
**ICD-10 code description**
Hyperparathyroidism and other disorders of parathyroid gland

## Primary outcomes

### 1

**Description**
Serum phosphate level
**Timepoint**
Twice a weeks for 3 months
**Method of measurement**
By standard kit in Imam Hossein hospital

### 2

**Description**
PTH level
**Timepoint**
Monthly for 3 months
**Method of measurement**

By standard kit in Imam Hossein hospital

**3**

**Description**
TG level
**Timepoint**
Start and end in 3 months
**Method of measurement**
By standard kit in Imam Hossein hospital

**4**

**Description**
LDL level
**Timepoint**
Start and end in 3 months
**Method of measurement**
By standard kit in Imam Hossein hospital

**5**

**Description**
HDL level
**Timepoint**
Start and end in 3 months
**Method of measurement**
By standard kit in Imam Hossein hospital

## Secondary outcomes

**1**

**Description**
Serum Calsium level
**Timepoint**
Twice a weeks for 3 months
**Method of measurement**
By standard kit in Imam Hossein hospital

## Intervention groups

**1**

**Description**
Intervention group (Group I) will receive nicotinic acid . Nicotinic acid will be started as 200 mg/day, patients will be controlled for nicotinic acid's side effects such as GI problems and thrombocytopenia. Calcium & phosphorous, PTH and lipid profile will be checked every other week. Nicotinic acid will be increased to 600 mg/day (200 mg additional per months). If serum phosphorous is between 3.5 – 4 mg/day, it will remain unchanged. Nicotinic acid will continue till 12 weeks.
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group (Group II) will receive placebo similar case group and will continue till 12 weeks.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Imam Hossein hospital of Shahroud
**Full name of responsible person**
Dr.Mohammad Bagher Sohrabi
**Street address**
Imam Hossein hospital, End Imam street, Shahroud,Iran
**City**
Shahroud

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Shahroud University medical and Sciences
**Full name of responsible person**
Dr. Mohammad Hasan Imamian
**Street address**
Vice chancellor for research, Shahroud University medical Sciences ,7th Tir squar, Shahroud
**City**
Shahroud
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Shahroud University medical and 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**
Shahroud University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Bagher Sohrabi
**Position**
General practitioner

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Other areas of specialty/work**
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**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*