

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of niacin on sodium, phosphorus, parathyroid hormone (PTH) and vitamin D levels in hemodialysis patients

Protocol summary

Study aim

Efficacy of Niacin in reduction of phosphate and PTH in hemodialysis patients

Design

Clinical trial, with parallel groups, double-blind, randomized, phase 3 on 60 patients.

Settings and conduct

Sixty hemodialysis patients of Hajar Hospital in Shahrekord Dialysis Center will be screened based on the latest phosphorus serum level in monthly tests and study inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 15 years, Phosphorus more than 4.5, At least six months have passed since the start of hemodialysis, No change in treatment and hemodialysis protocols in the last two weeks and Consent to participate in the study. Exclusion criteria: Pregnancy, Known liver diseases, Active peptic ulcer disease, Taking carbamazepine and Drug intolerance

Intervention groups

Intervention group: Niacin 50 mg tablets. Control group: placebo

Main outcome variables

Level of calcium, phosphate and PTH

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190702044076N2**

Registration date: **2022-11-09, 1401/08/18**

Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**

Update count: **0**

Registration date

2022-11-09, 1401/08/18

Registrant information

Name

Faranak sadat Filsous

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3778 8907

Email address

hamidnasri@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of niacin on sodium, phosphorus, parathyroid hormone (PTH) and vitamin D levels in hemodialysis patients

Public title

The effect of niacin on sodium, phosphorus, parathyroid hormone (PTH) and vitamin D levels

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 15 years Phosphorus more than 4.5 At least six months have passed since the start of hemodialysis No change in treatment and hemodialysis protocols in the last two weeks Consent to participate in the study

Exclusion criteria:	Pregnancy Known liver diseases Active peptic ulcer disease Taking carbamazepine Drug intolerance
Age	From 15 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Data analyser
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	The type of drug prescribed is randomized by simple randomization among the participants by using the RRAApp software. For this purpose, in the order of participation in the research, the participants will receive Niacin (N=30) or placebo (N=30) based on the group they are assigned by RRAApp software. Allocation concealment is not carried out. http://clinicalresearch-apps.com/RRAApp.html
Blinding (investigator's opinion)	Double blinded
Blinding description	Patients knowing about the study groups will not be informed about the allocation in treatment groups and this allocation will be done randomly. The statistical analyzer will receive the groups as A and B codes.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Shahrekord of Medical Sciences
Street address	Num 21/shahid yar mohammadi alley/Bagh ziar Blve
City	Esfahan
Province	Isfahan
Postal code	8177774564
Approval date	2022-06-22, 1401/04/01
Ethics committee reference number	

IR.SKUMS.REC.1400.079

Health conditions studied

1

Description of health condition studied

Dialysis

ICD-10 code

T81.502

ICD-10 code description

Unspecified complication of foreign body accidentally left in body following kidney dialysis

Primary outcomes

1

Description

Calcium

Timepoint

Before intervention, month 1, 2 and 3

Method of measurement

Blood sampling

2

Description

Parathyroid hormone

Timepoint

Before intervention, month 1, 2 and 3

Method of measurement

Blood sampling

3

Description

Phosphorus

Timepoint

Before intervention, month 1, 2 and 3

Method of measurement

Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group of patients will take 50 mg niacin tablets daily

Category

Treatment - Drugs

2

Description

Control group: This group of patients will receive placebo tablets similar to niacin tablets daily

Category
Placebo

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar hospital in Shahrekord
Full name of responsible person
Faranak Sadat Filsouf
Street address
Parastar street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435
Phone
+98 38 3222 5505
Email
Hajar-Hospital@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Masoumeh Moezzi
Street address
Rahmatiyeh Street
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Postal code
8815716191
Phone
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mmoezzi@skums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahrekrd University of Medical Science

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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Faranak Sadat Filsous
Position
General docter
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact

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Shahre-kord University of Medical Sciences
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Position
General docter
Latest degree
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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Faranak Sadat Filsous

Position

General doctor

Latest degree

Medical doctor

Other areas of specialty/work

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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