

# 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

|                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Exclusion criteria:</b>                    | Pregnancy Known liver diseases Active peptic ulcer disease Taking carbamazepine Drug intolerance                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Age</b>                                    | From <b>15 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Gender</b>                                 | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Phase</b>                                  | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Groups that have been masked</b>           | <ul style="list-style-type: none"> <li>Participant</li> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Sample size</b>                            | Target sample size: <b>60</b>                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Randomization (investigator's opinion)</b> | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Randomization description</b>              | 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.<br><a href="http://clinicalresearch-apps.com/RRAApp.html">http://clinicalresearch-apps.com/RRAApp.html</a> |
| <b>Blinding (investigator's opinion)</b>      | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Blinding description</b>                   | 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.                                                                                                                                                                                                                                                  |
| <b>Placebo</b>                                | Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Assignment</b>                             | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Other design features</b>                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Secondary Ids</b>                          | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Ethics committees</b>                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>1</b>                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Ethics committee</b>                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Name of ethics committee</b>               | Ethics committee of Shahrekord of Medical Sciences                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Street address</b>                         | Num 21/shahid yar mohammadi alley/Bagh ziar Blve                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>City</b>                                   | Esfahan                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Province</b>                               | Isfahan                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Postal code</b>                            | 8177774564                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Approval date</b>                          | 2022-06-22, 1401/04/01                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Ethics committee reference number</b>      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

|                                                                                                    |
|----------------------------------------------------------------------------------------------------|
| IR.SKUMS.REC.1400.079                                                                              |
| <b>Health conditions studied</b>                                                                   |
| <b>1</b>                                                                                           |
| <b>Description of health condition studied</b>                                                     |
| Dialysis                                                                                           |
| <b>ICD-10 code</b>                                                                                 |
| T81.502                                                                                            |
| <b>ICD-10 code description</b>                                                                     |
| Unspecified complication of foreign body accidentally left in body following kidney dialysis       |
| <b>Primary outcomes</b>                                                                            |
| <b>1</b>                                                                                           |
| <b>Description</b>                                                                                 |
| Calcium                                                                                            |
| <b>Timepoint</b>                                                                                   |
| Before intervention, month 1, 2 and 3                                                              |
| <b>Method of measurement</b>                                                                       |
| Blood sampling                                                                                     |
| <b>2</b>                                                                                           |
| <b>Description</b>                                                                                 |
| Parathyroid hormone                                                                                |
| <b>Timepoint</b>                                                                                   |
| Before intervention, month 1, 2 and 3                                                              |
| <b>Method of measurement</b>                                                                       |
| Blood sampling                                                                                     |
| <b>3</b>                                                                                           |
| <b>Description</b>                                                                                 |
| Phosphorus                                                                                         |
| <b>Timepoint</b>                                                                                   |
| Before intervention, month 1, 2 and 3                                                              |
| <b>Method of measurement</b>                                                                       |
| Blood sampling                                                                                     |
| <b>Secondary outcomes</b>                                                                          |
| empty                                                                                              |
| <b>Intervention groups</b>                                                                         |
| <b>1</b>                                                                                           |
| <b>Description</b>                                                                                 |
| Intervention group: This group of patients will take 50 mg niacin tablets daily                    |
| <b>Category</b>                                                                                    |
| Treatment - Drugs                                                                                  |
| <b>2</b>                                                                                           |
| <b>Description</b>                                                                                 |
| 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

**City**

Shahrekord

**Province**

Isfahan

**Postal code**

8815716191

**Phone**

+98 38 3333 9940

**Email**

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

**Street address**

No21/Shahid Yarmohammadi Ave/Bagh Ziar Blvd

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8815716191

**Phone**

+98 31 3778 8907

**Fax****Email**

hamidnasri@med.mui.ac.ir

**Person responsible for scientific 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

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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**

General Practitioner

**Street address**

No21/Shahid Yarmohammadi Ave/Bagh Ziar Blvd

**City**

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**Fax**

**Email**

hamidnasri@med.mui.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