

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effect of Biotin on the severity and frequency of muscle cramps in patients undergoing hemodialysis

#### Protocol summary

##### Study aim

The aim of this study was to determine the effect of biotin on the intensity and frequency of muscle cramps in hemodialysis patients in Sanandaj Tohid hospital.

##### Design

In this double-blind, controlled clinical trial, 22 patients with chronic renal failure under hemodialysis were randomly divided into intervention and control groups using blockade. Patients and researchers were unaware of how the patients were grouped, and one of the colleagues who was not sensitive to the study results collected and recorded all the information.

##### Settings and conduct

The site of the study was the hemodialysis center of Tohid Hospital in Sanandaj.

##### Participants/Inclusion and exclusion criteria

All patients with chronic renal failure under hemodialysis who referred to the hemodialysis center of Tohid Hospital in Sanandaj, and had muscle cramps at least once a week.

##### Intervention groups

In the intervention group, 1 mg of biotin was administered for 12 weeks. In the first week and 12th week, the levels of biotin were measured by ELISA method. In the control group, placebo was given.

##### Main outcome variables

Muscle Cramps

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130311012789N18**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **retrospective**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

##### Registration date

2018-04-28, 1397/02/08

##### Registrant information

###### Name

Masoud Rasolabady

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 87 3366 4654

###### Email address

rasolabady@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-05, 1396/10/15

##### Expected recruitment end date

2018-03-16, 1396/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Biotin on the severity and frequency of muscle cramps in patients undergoing hemodialysis

##### Public title

The effect of Biotin on muscle cramps in patients undergoing hemodialysis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Patients with chronic renal failure Muscle cramps at least

once a week

**Exclusion criteria:**

Patient unwillingness to participate in the study  
Sensitivity to Biotin  
Necessity of taking vitamin C, vitamin E and carnitine

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **22**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were allocated into intervention and control groups using randomized block design

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and researchers were unaware of patients grouping and all information was gathered by a colleague who was not sensitive to the results of the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

**Street address**

Pasdaran Ave.

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

66177-13446

**Approval date**

2017-12-30, 1396/10/09

**Ethics committee reference number**

IR. MUK. REC. 1396/283

**Health conditions studied**

1

**Description of health condition studied**

Muscle Cramps

**ICD-10 code**

R25.2

**ICD-10 code description**

Cramp and spasm

**Primary outcomes**

1

**Description**

Severity , frequency and duration of muscle cramps

**Timepoint**

The first week and the twelfth week

**Method of measurement**

The severity of muscle cramps were measured using the visual analogue scale of pain and the number and duration of contractions were measured using seconds, minutes and hours.

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: In the intervention group, 1 mg of biotin was administered for 12 weeks.

**Category**

Treatment - Drugs

2

**Description**

Control group: The control group received placebo.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Tohid hospital

**Full name of responsible person**

Sara Mohammadzadeh

**Street address**

Basij Sq., Geryashan St.,

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sara66\_med@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Rasool Nasiri Kalmarzi

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Sanandaj University of Medical Sciences

**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**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Sara Mohammadzadeh

**Position**

Internal Medicine resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**

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Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Nephrologist

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Part of the data is shareable.

**When the data will become available and for how long**

One year after the publication the data will be available.

**To whom data/document is available**

En Researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Meta-analysis is allowed on the data of this study

**From where data/document is obtainable**

Dr. Sara Mohammadzadeh, Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran ,Email: sara66\_med@yahoo.com

**What processes are involved for a request to access data/document**

After one year of publishing the article and publishing the results, those who need the data of this study, could apply via email .

**Comments**