

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)

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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

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Basij Sq., Geryashan St.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

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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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Position

Assistant Professor

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Subspecialist

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Person responsible for updating data

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Full name of responsible person

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Position

Internal Medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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