Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of vitamin E on muscle cramps, appetite and pruritus in hemodialysis patients in dialysis wards of hospitals affiliated to Islamic Azad University of Tehran

Protocol summary

Study aim
Study the effect of vitamin E in reducing muscle cramps and pruritus in hemodialysis patients referring to hospitals affiliated to Tehran Azad University.

Design
Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 3 on 40 patients. Excel rand function was used for randomization.

Settings and conduct
In the dialysis wards of the hospitals affiliated to the Islamic Azad University of Tehran, the two case and control groups will be randomly given vitamin E and placebo for 12 weeks and will be asked a questionnaire at the beginning and end of the study. Patients, physician, researcher and statistician They will be unaware of the type of medicine they will be taking.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age range 18 to 90 years old; signing of informed consent form; starting dialysis at least three months ago; no history of taking vitamin E at the beginning and before the study; no history of eczema; no history of liver disease; no history of chronic gastrointestinal disease; no history of hypothyroidism; no history of parathyroid hormone above 300 and phosphorus above 6. Exclusion criteria: allergy to vitamin E capsules or placebo; pregnancy or lactation.

Intervention groups
In this randomized study, we have two case and control intervention groups, which we will give 400 units of vitamin E once daily to the case group and placebo once daily to the control group for 12 weeks.

Main outcome variables
Muscle cramps, itching and appetite

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150706023084N10**
Registration date: **2021-10-09, 1400/07/17**
Registration timing: **prospective**

Last update: **2021-10-09, 1400/07/17**
Update count: **0**

Registration date
2021-10-09, 1400/07/17

Registrant information

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Name of organization / entity
AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-10, 1400/07/18

Expected recruitment end date
2021-12-09, 1400/09/18

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of vitamin E on muscle cramps, appetite and pruritus in hemodialysis patients in dialysis wards of hospitals affiliated to Islamic Azad University of Tehran

Public title

Trial of vitamin E on pruritus, appetite and muscle cramps in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic kidney disease in the end stages Hemodialysis patients Age range 18 to 90 years old Signature informed consent form Start dialysis at least three months ago

Exclusion criteria:

History of thyroid disease Use of vitamin E Pregnancy Allergy to vitamin E or placebo History of chronic gastrointestinal disease History of chronic dermatologic disease History of liver disease such as cholestasis

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Sample selection and allocation in this study was done randomly with the help of rand function of Excel software. With the help of this software, the sequence of drug and placebo distribution was determined between the two groups of patients and with the help of someone outside the study, the groups receiving the drug and placebo were divided according to the mentioned sequence and the desired compounds were delivered to the patients.This information will be recorded and maintained by the said person until the end of the research.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the physician, researcher, data analyst, and patient taking the drug are unaware of the type of combination they will be taking (drug or placebo) and do not understand what combination they are receiving. The recipients of the drug and placebo were divided and the desired compounds were delivered to the patients and this information will be recorded and kept by the said person until the end of the research.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Department of Pharmaceutical Sciences, Tehran Islamic Azad University of Medical

Street address

No.99, Yakhchal street, Dr.Shariati Avenue

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2021-09-13, 1400/06/22

Ethics committee reference number

IR.IAU.PS.REC.1400.172

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Muscle cramp score

Timepoint

The time periods of muscle cramp severity were measured at the beginning of the study (before the intervention) and 12 weeks after the start of vitamin E use.

Method of measurement

In the study "the effect of vitamin E supplement on muscle cramps and itching and appetite in hemodialysis patients" how to measure muscle cramps is a questionnaire of professors of Tarbiat Modares University in relation to the evaluation of muscle cramps.

2

Description

Itching score

Timepoint

The time periods of itching severity were measured at the beginning of the study (before the intervention) and 12 weeks after the start of vitamin E use.

Method of measurement

In the study "The effect of vitamin E supplementation on muscle cramps and itching and appetite in hemodialysis patients" is yusovich questionnaire on how to measure itching.

3

Description

Appetite score

Timepoint

The appetite changes were measured at the beginning of the study (before the intervention) and 12 weeks after the start of vitamin E use.

Method of measurement

In the study "The effect of vitamin E supplementation on muscle cramps and itching and appetite in hemodialysis patients" is Bacter and Doyer questionnaire on how to measure appetite .

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 hemodialysis patients who will receive 400 units of vitamin E daily after lunch for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: 20 hemodialysis patients who will receive placebo of vitamin E contains oral paraffin daily after lunch for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali Hospital, Tehran

Full name of responsible person

Dr. Farahnaz Pasha

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At the beginning of Damavand Street, Imam Hossein Square

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2

Recruitment center

Name of recruitment center

Farhikhtegan hospital,Tehran

Full name of responsible person

Dr.Farahnaz Pasha

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Farshad Hashemian

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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

Islamic Azad University

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
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Maryam Shiehmorteza
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Person responsible for updating data

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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