

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Omega3 on uremic pruritus and sleep quality in patients treated with hemodialysis

Protocol summary

Summary

The study was a randomized clinical trial and to cross over is executed. The aim of this study was to determine the efficacy of omega-3 and Cetirizine of uremic pruritus in hemodialysis patients is the quality of sleep. First, patients with uremic pruritus in dialysis centers affiliated to University of Medical Sciences anymore hemodialysis are identified and then put them in a random order 52 if you wish to participate in the design and inclusion criteria itching more than 8 weeks, the lack of skin irritation, lack of sensitivity to omega-3, a lack of malabsorption or gastrointestinal disease, such as chronic diarrhea more than 2 weeks and no anticoagulation or antiplatelet enrolled in the study and in the case of drug intolerance, kidney transplantation, use of antihistamines or gabapentin , anemia with hemoglobin less than 7 g per deciliter, PTH greater than 300 micrograms per liter F INR, and prohibiting its use of antihistamines (blurred vision, glaucoma, etc.) are excluded. Group therapy (26) Omega-3 capsules, 1000 mg, 3 per day and Cetirizine 5 mg, 3 times a week and the control group (n = 26) standard treatment with Cetirizine 5 mg, 3 times a week for 6 weeks will. After a week of the lack of medicine, the two groups are reversed. And 6 weeks alternatives are used. The severity of itching and sleep quality 3 times (baseline and end of each phase of treatment is control.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040433206N1**

Registration date: **2017-05-10, 1396/02/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-10, 1396/02/20

Registrant information

Name

mansooreh heydarbeyki

Name of organization / entity

University of Medical Sciences anymore

Country

Iran (Islamic Republic of)

Phone

+98 32395054

Email address

m.heydarbeyki@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

. This is a master degree student's thesis are sponsored by University of Medical Sciences anymore done Summary *

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2017-08-04, 1396/05/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Omega3 on uremic pruritus and sleep quality in patients treated with hemodialysis

Public title

The effect of Omega3 supplementation on uremic pruritus and sleep quality

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: 1. Age over 18 years 2. patients with chronic renal failure 3. The dialysis time per session, frequency of dialysis per week are the same in both groups. Exclusion criteria: 1. patients younger than 18 years 2. Patients who have used other anti-itch medication and treatment has been effective. 3. The patient's unwillingness to continue the research. 4- malabsorption or any digestive problems (such as chronic diarrhea more than 2 weeks). 5. skin disease that cause itching dermatologist discretion and is not related uremic pruritus. 6. contraindicated antihistamines (blurred vision, glaucoma, prostate, dementia, neurological disorders -Zlany) 7. received drugs or treatments that have the same itch topical emollients, UV rays and effective. 8Sensitivity to omega-3. 9. The patient died

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

n this study, patients are not deprived of the standard treatment of uremic pruritus. The intervention group received treatment with omega-3 Cetirizine and control group to receive treatment with Cetirizine alone.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Medical Sciences anymore

Street address

haft tir squar University of Medical Sciences anymore

City

shahrood

Postal code

Approval date

2017-03-07, 1395/12/17

Ethics committee reference number

ir.shmu.rec.1395.187

Health conditions studied

1

Description of health condition studied

end stage renal disease

ICD-10 code

n18.0

ICD-10 code description

renal end stage(failer

Primary outcomes

1

Description

Uremic pruritus

Timepoint

3 times (baseline, 6 weeks after the intervention, and at the end of the study)

Method of measurement

35/5000 Did you mean: پرسشنامه خارش یوسپیوویج Save
Reset Itching questionnaire Yvsypvych

Secondary outcomes

1

Description

sleep quality

Timepoint

3 times (baseline, 6 weeks after the end of the study)

Method of measurement

Pittsburgh Sleep Questionnaire

Intervention groups

1

Description

Intervention group receive omega 3 g 3 times a day and Cetirizine 5 mg 3 times a week for 6 weeks, and control group receive standard treatment (Cetirizine 5 mg 3 times a week) for 6 weeks will receive.

Category

Treatment - Drugs

2

Description

Control group: standard treatment with Cetirizine 5 mg, 3 times a week for 6 weeks to receive.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein hospital anymore

Full name of responsible person

dr monireh amerian

Street address

shahrood emam street emam hosain squar

City

shahrood

2

Recruitment center

Name of recruitment center

28/5000 Red Crescent Dialysis Center anymore

Full name of responsible person

mansooreh heydarbeyki

Street address

Street 22 St. Azadegan commercial complex in its treatment of dialysis centers Razavian

City

shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technological Sciences anymore

Full name of responsible person

MH Emamian

Street address

haft tir squar

City

shahrood

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Technological Sciences anymore

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

School of Nursing and Midwifery University of Medical Sciences King

Full name of responsible person

mansooreh heydarbeyki

Position

A graduate student in intensive care nurse

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Nursing and midwifery anymore

Full name of responsible person

Doctor Hossein Ebrahimi

Position

PhD

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Full name of responsible person

mansooreh heydarbeyki

Position

Graduate student nursing care

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty