

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of omega-3 fatty acids on uremic pruritus in chronic hemodialysis patients

Protocol summary

Study aim

Effects of omega-3 fatty acids on uremic pruritus in chronic hemodialysis patients

Design

Randomized , Double blind, Clinical trial with control group, with parallel groups, with 60 hemodialysis patients, based on previous studies,

Settings and conduct

Patients with chronic renal failure and reflux pruritus undergoing hemodialysis in the hemodialysis department of Sina Hospital; None of the treatment staff and patients were aware of which patients received medication or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; initiation of hemodialysis for at least 3 months and 3 times a week ; Kt / V above 1.2 Exclusion criteria: Other causes of itching, except kidney failure ; Pregnancy ; no active, uncontrolled or severe chronic inflammatory diseases ; Hemoglobin less than 10 g / dL ; bleeding disorder (including coagulopathies) or high risk of bleeding ; Receiving Omega-3 or any supplement containing omega-3 in the last 3 months ; Receiving drugs that affect inflammatory factors in the last 6 weeks ; Abuse of alcohol and other substances that cause dependency

Intervention groups

The treatment group includes 30 patients who receive omega-3 fatty acids daily for 3 months. The control group, which included 30 patients receiving placebo for 3 months.

Main outcome variables

Pruritus score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170609034406N2**

Registration date: **2018-08-29, 1397/06/07**

Registration timing: **retrospective**

Last update: **2018-08-29, 1397/06/07**

Update count: **0**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Afshin Gharekhani

Name of organization / entity

Faculty of Pharmacy/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Drug Applied Research Center of Tabriz University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of omega-3 fatty acids on uremic pruritus in chronic hemodialysis patients

Public title

Effect of omega-3 fatty acids on uremic pruritus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Age over 18 years ; Beginning hemodialysis for at least 3 months and three times per week ; Ability to understand and sign consent form ; Use of biocompatible dialysis membrane. Properly functioning arteriovenous fistula or catheter function; Dialysis adequacy above 1.2.

Exclusion criteria:

Exclusion criteria : Other causes of itching, except kidney failure ; Pregnancy ; The presence of any chronic, active, uncontrolled or severe chronic inflammatory disease (autoimmune diseases, connective tissue disease, malignancy, HIV, liver disease and pulmonary disease) ; presence of chronic infection or acute infection in the last month ; Hemoglobin less than 10 g / dL ; Co-presence in another trial ; Medical history (such as heart attack) or surgical in the last 3 months ; Symptoms of malabsorption ; Bleeding disorders (Includes coagulopathies) or high risk of bleeding ; Change in diet in the last 1 month; Consumption of Omega-3 or any supplement containing omega-3 in the last 3 months. ; Intolerance or susceptibility to drug ; Receiving drugs that have an effect on inflammatory factors (corticosteroids or other immunosuppressive drugs, non-steroidal anti-inflammatory drugs, contraceptives, pentoxifylline) in the last 6 weeks; Concomitant use of methyl dopa, cimetidine and serotonergic drugs such as triptans, tramadol, tryptophan and linzolid ; Use of warfarin ; Abuse of alcohol and other substances that cause dependence.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Permuted Block Randomization method was used for entering patients in control and treatment groups. In this method, each block contained an equal number of treatment groups and control group. Random numbers in this study were given using the Excel program to determine random blocks and random groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was conducted in a single blind clinical trial.

None of the people distributing drugs and patients were aware of which patients received the drug or placebo, and were only diagnosed with the numbers given by the system to the patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

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No 2 Central Building , Tabriz University of Medical Sciences , Golgasht Street , Tabriz

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Province

East Azarbaijan

Postal code

5165665931

Approval date

2016-10-10, 1395/07/19

Ethics committee reference number

IR.TBZ.REC.1395.795

Health conditions studied**1****Description of health condition studied**

Pruritus

ICD-10 code

L29.8

ICD-10 code description

Other pruritus

2**Description of health condition studied**

End Stage Renal Disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

pruritus score

Timepoint

Before intervention. Six weeks after the intervention. At the end of the intervention.

Method of measurement

Standard questionnaire

Secondary outcomes

1

Description

Hemoglobin level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Hemiglobincyanide(HiCN) method

2

Description

Serum Creatinine level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Jaffe method

3

Description

Serum phosohorus level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Colorimetric method

4

Description

Serum Calcium Level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Colorimetric method

5

Description

Blood Urea nitrogen

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Enzymatic method

6

Description

Cholesterol level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Enzymatic method

7

Description

Triglyceride level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Enzymatic method

8

Description

Serum Ferritin level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

ELISA Kit

9

Description

Serum Iron level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Colorimetric method

10

Description

Parathyroid Hormone level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Immunoassay (Analytical methods)

11

Description

C_Reactive protein level

Timepoint

Immediately before the intervention, in the second month of intervention, after the intervention

Method of measurement

Latex agglutination method

Intervention groups

1

Description

The treatment group consists of 30 patients receiving 1200 mg of omega-3 fatty acids daily for 3 months.

Category

Treatment - Drugs

2

Description

The control group consisted of 30 patients who received 1200 mg orally daily for a period of 3 months, which, apart from the active ingredient, were similar to omega-3 capsules.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Afshin Gharekhani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Afshin Gharekhani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Demographic data and main outcomes will be shared.

When the data will become available and for how long

Data files will become available 6 months after publication.

To whom data/document is available

It will be only available for people working in academic institutions.

Under which criteria data/document could be used

All of the data can be freely used if the citation is appropriately considered.

From where data/document is obtainable

The applicants will be referred to Research Vice-chancellor.

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

All of the requested data should be mentioned in a application letter which will be sent to the Research Vice-chancellor of Tabriz University of Medical Sciences.

Comments