Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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 linzolide ; 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
Street address
No 2 Central Building , Tabriz University of Medical Sciences , Golgasht Street , Tabriz
City
Tabriz
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
Enzymaticl 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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rashidi@tbzmed.ac.ir
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
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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