Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of omega-3 supplement on uremic pruritus in hemodialysis patients

Protocol summary

Study aim
Determination of effect of omega-3 supplement on uremic pruritus in hemodialysis patients

Design
Randomised clinical trial with control group and blinded outcome , that assessor and patient and statistician were blinded on 64 hemodialysis patients with uremic pruritus(32 patients in intervention group with omega-3 and 32 patients in placebo group), that were selected by Allocation Concealment.

Settings and conduct
This study was done in hemodialysis ward of Emam Khomeini and Razi hospital of Ahwaz. Patients were divided into control and intervention groups randomly by using blocks of six for allocation concealment.To reduce the risk of bias, patients and assessor and statistician were blinded to know the type of treatment assigned to each person and that which patient was in which group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: hemodialysis patients with uremic pruritus who were more than 18 years old Exclusion criteria: patients who were suffered from skin diseases or liver diseases or malignancy or allergy to omega-3. If there were any change in their treatment (such as kidney transplantation) they were excluded from the study.

Intervention groups
Hemodialysis patients with uremic pruritus were over 18 years old and their hemodialysis were more than three months and didn't have liver diseases, skin diseases, malignancy and allergy to Omega-3 supplements were divided into control and intervention groups randomly by using blocks of six for allocation concealment. Patients in the intervention group were received 2gr Omega-3 orally , single dose daily before lunch for three weeks. Patients in the control group were received placebo orally, single dose daily before lunch as well.Placebo capsules were similar to Omega-3 capsules in color, shape, size and taste.

Main outcome variables
Pruritus severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171220037968N1**
Registration date: **2018-04-27, 1397/02/07**
Registration timing: **retrospective**

Last update: **2018-04-27, 1397/02/07**
Update count: **0**

Registration date
2018-04-27, 1397/02/07

Registrant information

Name
Parastoo Lakhaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-30, 1396/07/08

Expected recruitment end date
2018-01-15, 1396/10/25

Actual recruitment start date
2017-11-29, 1396/09/08

Actual recruitment end date
2018-02-14, 1396/11/25

Trial completion date
empty

Scientific title
Effect of omega-3 supplement on uremic pruritus in hemodialysis patients

Public title
Effect of omega-3 on uremic pruritus hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All of hemodialysis patients with uremic pruritus that their hemodialysis were started at least since three months ago

Exclusion criteria:
Patients with skin disease Patients with liver disease Patients with malignancy Patients who were allergic to omega-3

Age
From **19 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Actual sample size reached: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
At the beginning of the study, patients equally were divided into two groups (intervention with omega-3 group and placebo group) that used anti pruritis agents approximately the same. Sampling of patients who entered the study with a Non-probabilistic sampling method was done sequentially. It means that from the beginning of study, all patients who had Inclusion criteria and didn't have exclusion criteria, were selected as sample and this was continued to reach the final sample size. Allocation of patients into each groups(intervention and placebo)was done by the Randomized Block Design (each block consist of six patients). Finally, patients were divided into two main groups (intervention and control group). To increase assurance and preventing of bias Allocation Concealment were used and unique code were given to each person.

Blinding (investigator's opinion)
Double blinded

Blinding description
To reduce the risk of bias, patients and assessor and statistician were blinded to know the type of treatment assigned to each person and that which patient was in which group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Golestan St., Jundishapur University of Medical Sciences, Vice Chancellor for Research and Technolog

City
Ahvaz

Province
Khouzestan

Postal code
15794-61357

Approval date
2017-07-29, 1396/05/07

Ethics committee reference number
IR.AJUMS.REC.1396.631

Health conditions studied

1

Description of health condition studied
Hemodialysis patients

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Degree of pruritus in hemodialysis patients

Timepoint
Before and 3 weeks after studing

Method of measurement
5D ITCH SCALE Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Omega-3 capsule (1gr) that its trade name was OmegaREX made by Daana Pharma Co. was

used 2gr single dose before lunch along three weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (1gr)that made by Faculty of Pharmacy, Ahvaz Jundishapur University of Medical Sciences with lactose and Avesil was used 2gr single dose before lunch along three weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis ward of Ẹmam khomeini Hospital of Ahvaz

Full name of responsible person

Dr. Shokouh Shayanpour- Assistant professor

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2

Recruitment center

Name of recruitment center

Hemodialysis ward of Razi Hospital of Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ḍr. Hatam Boustani

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Shokouh Shayanpour

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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