Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of omega3 on pruritus score in patients under peritoneal dialysis

Protocol summary

Summary

Pruritus is a common complaint in patients under maintenance dialysis. One of the proposed etiologies for pruritus in these patients is the inflammatory mediator derived from abnormal metabolic of fatty acids in ESRD patient. Considering the fact that EPA (eicosa pentatonic acid) which is direct metabolite of omega3 has anti-inflammatory and anti-pruritus activity and although its low concentration in plasma of ESRD patient, we conducted this study to evaluate the efficacy of omega3 in the management of pruritus in patients under peritoneal dialysis. This is a double-blind, placebo-controlled, randomized trial which lasted 14 weeks. In this study, patients with ESRD that were on peritoneal dialysis at least for a months and were not receiving any other anti-itching drugs and weren't sensitive to omega3 were included. Patients waiting for transplantation, having hyperparathyroidism or increased phosphatase or PT or INR are excluded. 20 subjects in the intervention group received 3 capsules of omega3 (1000 mg) and 20 subjects in the control group received placebo. Itching was measured before and every 2 week after beginning of intervention by VAS method and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808202370N5**
Registration date: **2012-01-22, 1390/11/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-22, 1390/11/02

Registrant information

Name

Mojgan Mortazavi

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2009-08-20, 1388/05/29

Expected recruitment end date

2010-02-18, 1388/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of omega3 on pruritus score in patients under peritoneal dialysis

Public title

Evaluation of the effect of omega3 on pruritus in patients under peritoneal dialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Being under maintenance dialysis for at least one month; Not being under other drug treatment for pruritus; Having pruritus for at least 8 wk; No sensitivity to omega3; Volunteer to participate.

Exclusion criteria: Non compliance with drug; Renal transplantation before end of therapy; anemia (Hb<7); Hyperparathyroidism (parathormone >300 eq/ml or phosphorus >7mg/dl); PT & INR rising.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan university of Medical Sciences

Street address
Vice Chancellor for Research, Isfahan Univrsity of Medicines

City
Isfahan

Postal code

Approval date
1990-01-01, 1368/10/11

Ethics committee reference number
288273

Health conditions studied

1

Description of health condition studied
Pruritus in peritoneal Patients

ICD-10 code
N18.0

ICD-10 code description
End-stage renal disease

Primary outcomes

1

Description
Decrease in Pruritus Score

Timepoint
every 2 week

Method of measurement
visual Analog scale

Secondary outcomes

1

Description
coagulopathy

Timepoint
every month

Method of measurement
PT and INR

Intervention groups

1

Description
cap omega3 1000 mg TDS

Category
Treatment - Drugs

2

Description
placebo TDS

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra University Hospital

Full name of responsible person
Dr Mojgan Mortazavi

Street address
Internal Medicine Department, Alzahra Hospital, Soffeh Ave.

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, School of Medicine, Isfahan University of Medical Sciences

Full name of responsible person
Vice Chancellor for Research ,Dr Peiman Adibi
Street address
Vice Chancellor for Research, School of Medicine, Isfahan University of Medical Sciences, Hezar Jarib St
City
Isfahan
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, School of Medicine, Isfahan University of Medical Sciences
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
Isfahan University of Medical Sciences
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Web page address

Person responsible for updating data

Contact

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