

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of Omega-3 on pruritus scale in hemodialysis patients

Protocol summary

Summary

End stage renal disease (ESRD) is a condition that patients complain from pruritus due to toxins accumulation. The aim of this study is to investigate the effects of dietary Omega-3 fatty acid supplementation on pruritus scale and serum level of Prostaglandin E2 in hemodialysis patients. 40 hemodialysis patients who were on hemodialysis (more than 3 months), suffering pruritus for more than eight weeks, and no history of skin diseases leading to pruritus before renal failure were enrolled. Patients with anemia (Hb<7g/dL), hyperphosphatemia (p>7mg/dL), PTH>300 microg/L, anticoagulants use, allergic reaction to omega-3 and gastrointestinal complications (e.g. diarrhea for more than two weeks) were excluded. The patients were randomly assigned to two groups of omega-3-placebo (20 patients) and placebo-omega-3 (20 patients). Patients in first group, consumed fish oil capsules (1000mg, three times a day, manufactured by Zahravi Pharmaceutical) for 4 weeks and after a 6 weeks washout period, they took placebo for another 4 weeks. The same was performed in second group, but in the reverse order. Pruritus score was evaluated each 2 weeks and serum levels of Prostaglandin E2 was recorded at the beginning and end of each treatment period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311152417N14**
Registration date: **2016-10-03, 1395/07/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-03, 1395/07/12

Registrant information

Name

Firouzeh Moeinzadeh

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Omega-3 on pruritus scale in hemodialysis patients

Public title

Effect of Omega-3 on pruritus scale in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: consent for cooperation; hemodialysis for at least 3 months; pruritus duration > 8 weeks; without any dermatologic problems; no hypersensitivity to omega-3; no malabsorption or other gastrointestinal

problems (chronic diarrhea >2 weeks); not using anticoagulant and antiplatelet drugs. Exclusion criteria: incompliance; kidney transplantation; antihistamin or Gabapentin using; anemia (Hb<7g/dL); PTH > 300microg/L ; Phosphorus >7mg/dL ; INR rising

Age

From **16 years** old to **99 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Vice Chancellor for Research,
Isfahan University of Medical Sciences

Street address

Hezar jarib street

City

Isfahan

Postal code

Approval date

2013-07-06, 1392/04/15

Ethics committee reference number

392301

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease

ICD-10 code

N18.0

ICD-10 code description

End Stage Renal Disease

Primary outcomes

1

Description

Pruritus score

Timepoint

At the begining, every 2 weeks and end of study

Method of measurement

Questionnaire (visual analog scale)

2

Description

Serum Prostaglandin E2

Timepoint

At the begining and end of study

Method of measurement

ELISA Kit,

Secondary outcomes

empty

Intervention groups

1

Description

Cap Omega-3 1000mg, 3 capsules per day for 2 months
manufactured by Zahravi company

Category

Treatment - Drugs

2

Description

Cap placebo, 3 capsules per day for 2 months
manufactured by Zahravi company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nour Hospital, Hemodialysis centre

Full name of responsible person

Dr Masoud Moghtaderi

Street address

Ostandari Street

City

Isfahan

2

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

Dr. Masoud Moghtaderi
Street address
Ibne Sina Street
City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancell for Research, Isfahan University of
Medical Sciences
Full name of responsible person
Dr. Peyman Adibi
Street address
Isfahan University of Medical Sciences, Hezar Jarib
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Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancell for Research, 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

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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