

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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)

##### Phone

+98 31 1260 2593

##### Email address

m\_mortazavi@med.mui.ac.ir

##### 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*

m\_mortazavi@med.mui.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Mojgan Mortazavi

**Position**

Associate Prof. Nephrology

**Other areas of specialty/work****Street address**

Internal Medicine Department, Alzahra Hospital,  
Soffeh Ave.

**City**

Isfahan

**Postal code****Phone**

+98 311625555

**Fax****Email**

m\_mortazavi@med.mui.ac.ir

**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

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**Fax****Email****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*