Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing effect of topical and oral flaxseed-oil on pruritus severity of hemodialysis patients.

Protocol summary

Summary

Some studies showed that fatty acids deficiency were related to pruritus in hemodialysis patients. Aim of this study is compare the effect of topical and oral flaxseed-oil on pruritus severity of hemodialysis patients. Patients with history of at least 6 months hemodialysis; three times hemodialysis in a week for 3-4 hours in each session; phosphorous level below 6 mg/dl and parathyroid hormone level below 600 pg/ml will be selected. Patients who are treated with warfarin, hemoglobine level below 10gr/dl and pruritus related to other disorders are excluded. Eligible patients randomly assigned in three groups. Patients in group one are received routine care. In group two, patients are received oral flaxseed-oil 1 gr three times a day for 6 weeks. Patients in group three are received topical flaxseed-oil 5 cc in two times a day for 6 weeks. Severity of pruritus in three groups are compared with each others.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602116481N9**
Registration date: **2016-06-16, 1395/03/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-06-16, 1395/03/27

Registrant information

Name

Mohsen Soleimani

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4190

Email address

soli257@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-06-25, 1395/04/05

Expected recruitment end date

2017-12-26, 1396/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of topical and oral flaxseed-oil on pruritus severity of hemodialysis patients.

Public title

Comparing effect of topical and oral flaxseed-oil on pruritus severity of hemodialysis patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: At least 6 month history of hemodialysis; hemodialysis for three times a week for 3-4 hours; phosphor of serum below 6 mg/dl; parathyroid hromone level below 600 pg/ml. Exclusion criteria: Pruritus realted to hepatic and metabolic disorders; systemic disorders such as malignancy, hepatitis, cholestasis; hemoglobin level below 10g/dl; warfarin therapy; renal transplantation during study; allergy to oils.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences

City

Semnan

Postal code

Approval date

2016-05-24, 1395/03/04

Ethics committee reference number

IR.SEMUMS.REC.1395.24

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Pruritus

Timepoint

Every 2 weeks for 6 weeks

Method of measurement

The 5-D itch scale

Secondary outcomes

1

Description

Hemoglobine

Timepoint

Every 3 weeks for 6 weeks

Method of measurement

Complete blood count

Intervention groups

1

Description

Topical flaxseed-oil 5cc two times a day for 6 weeks.

Category

Treatment - Other

2

Description

Oral flaxeed-oil 1gr three times a day for 6 weeks

Category

Treatment - Other

3

Description

Routine cares

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Soodeh hospital

Full name of responsible person

Rahimeh Nabavi

Street address

Islam-shahr Vavan town

City

Islam-shahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Ali Rashidy-pour

Street address

Vice-chancellor, Semnan University of Medical Sciences

City
Semnan

Grant name

Grant code / Reference number

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

Title of funding source
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Mohsen Soleimani

Position
PhD in nursing

Other areas of specialty/work

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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