

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of the effects of Cannabis sativa L. seed oil on the serum concentration of interleukin 6 and interleukin 33 in hemodialysis patients

Protocol summary

Summary

Objectives: Evaluation of the anti-inflammatory effects of Cannabis sativa seed oil in hemodialysis patients Design: This study is a randomized single blind (researchers who measure the serum concentration of interleukins and analyze the results do not have any information about the assignment of patients to each group) clinical trial. One hundred thirty hemodialysis patients from 2 dialysis centers will be entered to the study. Patients will be randomly assigned to the intervention or control group based on simple block randomization. Setting: The oil will be obtained by the cold pressing of the hemp seeds. Patients will receive 20 ml of the hemp seed oil per day in the intervention group. In the control group patients will receive no treatment. Participants: patients who are undergoing regular hemodialysis for at least 3 months will be recruited. Patients who have an infection or who are consuming immunosuppressive medications will be excluded. Main outcome measures: Primary outcome variables: The serum concentrations of interleukin 6 and interleukin 33. These variables will be measured by the ELISA kits. Secondary outcome variables: Adverse effects. This variable will be recorded based on the patients' reports.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031522637N3**
Registration date: **2017-05-01, 1396/02/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-01, 1396/02/11

Registrant information

Name

Naemeh Nikvarz

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5017

Email address

nnikvarz@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kerman University of Medical Sciences

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Cannabis sativa L. seed oil on the serum concentration of interleukin 6 and interleukin 33 in hemodialysis patients

Public title

Anti inflammatory effects of Cannabis sativa L. seed oil in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing regular hemodialysis for at least 3 months Exclusion criteria:

active infection; consuming immunosuppressive medications; autoimmune diseases

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **130**

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

Ethics committee of Kerman University of Medical Sciences

Street address

Vice chancellor for research, Ebn-e-Sina Street

City

Kerman

Postal code

7619813159

Approval date

2017-02-21, 1395/12/03

Ethics committee reference number

IR.KMU.REC.1395.864

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease (Hemodialysis)

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Serum concentration of interleukin-6

Timepoint

At baseline and at the end of the study

Method of measurement

ELISA kit

2

Description

Serum concentration of interleukin-33

Timepoint

At baseline and at the end of the study

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Adverse effects

Timepoint

During the study

Method of measurement

patient self report

Intervention groups

1

Description

Intervention group: Hemp seed oil, oral consumption, 20 ml/day for 2 months.

Category

Treatment - Drugs

2

Description

Control group: No treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Naemeh Nikvarz

Street address

Kowsar Boulevard

City

Kerman

2

Recruitment center

Name of recruitment center

Javad-ol Aemeh Dialysis Center

Full name of responsible person

Naemeh Nikvarz

Street address

25th Alley, North Aboozar Street

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Vice chancellor for research, Ebn-e-sina Street

City

Kerman

Grant name

Grant code / Reference number

95000041

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

Yes

Title of funding source

Vice chancellor for research, Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

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Position

Pharmacy student

Other areas of specialty/work

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Person responsible for updating data

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Position

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Web page address

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