

# 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**

Zahra Sharifi Negad

**Position**

Pharmacy student

**Other areas of specialty/work**

**Street address**

Faculty of pharmacy, Haft-Bagh road

**City**

Kerman

**Postal code**

7616911319

**Phone**

+98 34 3132 5000

**Fax**

+98 34 3132 5003

**Email**

zahrasharifi12@yahoo.com

**Web page address**

Not available

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Naemeh Nikvarz

**Position**

Clinical Pharmacy Specialist

**Other areas of specialty/work**

**Street address**

Faculty of Pharmacy, Haft Bagh Road

**City**

Kerman

**Postal code**

7616911319

**Phone**

+98 34 3132 5017

**Fax**

+98 34 3132 5003

**Email**

nnikvarz@kmu.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Naemeh Nikvarz

**Position**

Clinical Pharmacy Specialist

**Other areas of specialty/work**

**Street address**

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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*