

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Evaluating the effects of Descurainia Sophia on serum inflammatory markers and thirst alleviation in hemodialysis patients

#### Protocol summary

##### Study aim

Evaluating the effects of Descurainia Sophia (D.S) on serum inflammatory markers and thirst alleviation in hemodialysis patients

##### Design

Clinical trials with controlled group, crossover, triple blind, randomized clinical trials. sample size : 60 ;  
Randomization : Balanced block Randomization

##### Settings and conduct

Patients are randomly allocated into two experimental groups. In the group 1, the patients received D. Sophia powder (4 weeks) , then washout (2 weeks ) following by placebo( 4 weeks). In the group 2 as the same but in reverse direction. D. Sophia was prepared by admixing 2 g of D. Sophia powder and 0.5 g brown sugar. The placebo was prepared by combining 2 g starch powder and 0.5 g brown sugar. Blood samples are drawn in four steps. Study will be executed at Tehran Shahid modarres hospital and Babol Shahid Beheshti hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 to 70 years old; being on hemodialysis for more than 3 months;  $KT/V > 1.2$ ; Using AVF for Hemodialysis. Non-inclusion criteria: Sensitivity to D. Sophia or any herbal remedy; History of active infection in the past month; Unwillingness to participate in the study for any reason; Using permcath or AVG for hemodialysis; Hospital admission for any reason in past month or during the study period.

##### Intervention groups

The first intervention group (n = 30) initially received D. Sophia extract and received the placebo after the washout period. The second Intervention group (n = 30) received the placebo first and the post washout period, they received the D. Sophia extract placebo.

##### Main outcome variables

serum calcium level ; cholesterol level; triglyceride level; potassium level; sodium levels; malondialdehyde (MDA) level ; Total antioxidant capacity ; homocysteine levels ; Thirst scale score.

#### General information

##### Reason for update

##### Acronym

HDS

##### IRCT registration information

IRCT registration number: **IRCT20170725035305N3**

Registration date: **2019-08-09, 1398/05/18**

Registration timing: **retrospective**

Last update: **2019-08-09, 1398/05/18**

Update count: **0**

##### Registration date

2019-08-09, 1398/05/18

##### Registrant information

##### Name

Amirhesam Alirezaei

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2208 3095

##### Email address

aalirezaei@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

2019-01-05, 1397/10/15

##### Actual recruitment end date

2019-04-09, 1398/01/20

##### Trial completion date

2019-07-11, 1398/04/20

### Scientific title

Evaluating the effects of Descurainia Sophia on serum inflammatory markers and thirst alleviation in hemodialysis patients

### Public title

Descurainia Sophia in hemodialysis patients

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

age between 18 - 70 years old on hemodialysis for more than 3 months KT/V > 1.2 insensitive to D. Sophia or any herbal remedy no history of active infection in the past month using AVF for Hemodialysis

#### Exclusion criteria:

sensitivity to D. Sophia or any herbal remedy history of active infection in the past month unwilling to participate for any reason using permcath or AVG for hemodialysis hospital admission for any reason in past month and during the study period.

### Age

From **18 years** old to **70 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **0**

Actual sample size reached: **53**

More than 1 sample in each individual

Actual sample size in each individual: **4**

blood sample

### Randomization (investigator's opinion)

Randomized

### Randomization description

The method of balanced block randomization used with a block size of 4. For the allocation sequence, we applied computer-generated by random numbers. Medicines containing seed extract or placebos with the same shape and color numbered with a code in sealed envelopes. Each coded prepared medication with a label by one number from 1 to 60. The patients randomly allocated into two experimental groups: group 1(n=30) initially received Intervention D.S extract, and group2 (n=30 ) received placebo initially. Both groups were identical in terms of characteristics and comorbid conditions; the participants divided sequentially.The control group is assigned to "A" and the intervention group to "B", and then the two groups are divided into 6 blocks: (1) AAB,

(2) B A A, (3 (B), b), b), b), b), b), b) These blocks are randomly put together by computer and provide a chain of randomized groups (eg: B A B B A B B A B B A B B). Then the patients enter these groups in order of entry.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

During study period ,a nurse coordinated the study and registered the study codes and the nurse handed the labeled drugs over participants and collected all the data. The patients , investigators , laboratory staffs and supervisors all were blinded to treatment assignment and lab data measurements during the study.

### Placebo

Used

### Assignment

Crossover

### Other design features

prevention

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

##### Street address

7th Floor, Bldg No.2 , Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, chamran highway,Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

#### Approval date

2018-12-22, 1397/10/01

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1397.299

## Health conditions studied

### 1

#### Description of health condition studied

hemodialysis patients

#### ICD-10 code

N18.5

#### ICD-10 code description

Chronic kidney disease, stage 5

## Primary outcomes

## 1

### **Description**

MDA (Malondialdehyde)

### **Timepoint**

At the start of the study, before wash out, after wash out and at the end of the study

### **Method of measurement**

serum level and biochemistry analysis

## 2

### **Description**

Potassium serum level

### **Timepoint**

At the start of the study, before wash out, after wash out and at the end of the study

### **Method of measurement**

blood sample

## 3

### **Description**

Lipid profile

### **Timepoint**

At the start of the study, before wash out, after wash out and at the end of the study

### **Method of measurement**

blood sample

## 4

### **Description**

Total antioxidation capacity

### **Timepoint**

At the start of the study, before wash out, after wash out and at the end of the study

### **Method of measurement**

blood sample

## 5

### **Description**

Hemocystein serum level

### **Timepoint**

At the start of the study, before wash out, after wash out and at the end of the study

### **Method of measurement**

blood sampling

## **Secondary outcomes**

## 1

### **Description**

Thirst intensity

### **Timepoint**

At the start of the study, before wash out, after wash out and at the end of the study

### **Method of measurement**

using Visual Analogue Scale

## **Intervention groups**

## 1

### **Description**

The first intervention group (n = 30) initially received an extract of Descuria.Sophia containing 2 grams of D,Sophia powder and half a gram of brown sugar with 100 cc of water for 4 weeks, and after 2 weeks of washout period and followed by 4 weeks of placebo intake containing 2 grams of Starch powder and half a gram of brown sugar with 100 cc water.

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: The second intervention group (30 patients). At first, received 4 weeks of the placebo containing 2 grams of starch powder and half a gram of brown sugar with 100 cc of water, and after 2 weeks of washout period, followed by receiving Descuria.Sophia extract containing 2 grams of D.Sophia powder and half a gram of brown sugar received with 100 cc water for 4 weeks.

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Shahid Modaress hospital of Tehran

#### **Full name of responsible person**

Amirhesam Alirezaei

#### **Street address**

Shahid Modaress hospital , Kaaj square , Saadat Abad , Tehran

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1998734383

#### **Phone**

+98 21 2208 3112

#### **Email**

amirhesam124@gmail.com

## 2

### **Recruitment center**

#### **Name of recruitment center**

Shahid Beheshti Hospital of Babol

#### **Full name of responsible person**

Amirhesam Alirezaei

#### **Street address**

Shahid beheshti hospital , Sargord Ghasemi avenue , Babol , Mazandaran

**City**  
بابل  
**Province**  
Mazandaran  
**Postal code**  
4716681451  
**Phone**  
+98 11 3225 2071  
**Email**  
amirhesam124@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Amirhesam Alirezaei  
**Street address**  
Shahid Modaress hospital, after Kaaj square,  
Saadatabad, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1998734383  
**Phone**  
+98 21 2208 3112  
**Email**  
amirhesam124@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti University of Medical Sciences  
**Proportion provided by this source**  
30  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Amirhesam Alirezaei  
**Position**  
Associate professor  
**Latest degree**

Subspecialist  
**Other areas of specialty/work**  
nephrology  
**Street address**  
Shahid Modaress hospital, after Kaaj square,  
Saadatabad, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1998734383  
**Phone**  
+212 2083112  
**Email**  
amirhesam124@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Amirhesam Alirezaei  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
nephrology  
**Street address**  
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo  
Blvd, Velenjak, Tehran, Iran. Post Code: 19839-6311  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1998734383  
**Phone**  
+98 21 2208 3112  
**Fax**  
**Email**  
Amirhesam124@gmail.com  
**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Alirezaei Amirhesam  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
nephrology  
**Street address**  
Shahid Modaress hospital, after Kaaj square,

Saadatabad, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1998734383

**Phone**

+98 21 2208 3112

**Email**

amirhesam124@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All collected data can be shared after making participants unidentifiable.

**When the data will become available and for how long**

starting after publication

**To whom data/document is available**

people working in academic institutions

**Under which criteria data/document could be used**

Any types of analyses

**From where data/document is obtainable**

email

**What processes are involved for a request to access data/document**

less than 2 weeks

**Comments**