Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 exicuted 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 recieved 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

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Iran (Islamic Republic of)

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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 supervisers 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.

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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 followd 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,recieved 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 recieving Descuiria.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
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Name of recruitment center
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Sponsors / Funding sources

1

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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
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Associate professor
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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 c is an 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