Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of hydroalcoholic extract of Nasturtium officinale on level of vitamin C and E, protein carbonyl and inflammatory markers in chronic hemodialysis patients.

Protocol summary

Study aim
Determining the effect of hydroalcoholic extract of Nasturtium officinale on the levels of vitamins C and E, carbonyl protein and inflammatory markers in patients undergoing chronic hemodialysis

Design
A randomized controlled clinical trail with parallel, double_blind, randomized, phase 2 group on 70 patients used the random allocation rule.

Settings and conduct
Patients undergoing chronic hemodialysis referred to Shahid Beheshti Hospital in Yasuj are randomly divided into two groups by random allocation method. patients in the intervention group (35 patients) receive watercress extract capsules and in the control group (35 patients) receive placebo (flour capsules) in the same form and amount. The treatment protocol in both groups in 500 mg capsules twice a day. Follow-up of patients is done every week during treatment and 8 weeks after the end of treatment. It should be noted that the patient and the researcher will not know about the assignment of groups and it is a double-blind study.

Participants/Inclusion and exclusion criteria
Inclusion criteria;18 years of age and older; Receive hemodialysis at least twice a week for about 3 months; Negative history of taking drugs that affect inflammatory markers such as corticosteroids and nonsteroidal anti inflammatory drugs (NSAIDs) in a recent month Exclusion criteria: Causes unpredictable drug side effects; Patients who refused to cooperate and continue the study and received the drug for less than 4 weeks; Development of active infectious diseases, cirrhosis and congestive heart failure and malignancy during the study and the need for kidney transplantation; Malnutrition and cachexia (body mass index less than 18 kg / m2); Albumin less than 3

Intervention groups
Intervention group: hydroalcoholic extract of watercress
Control group:Capsules containing flour

Main outcome variables
Carbonyl protein IL-6 TNF-α Vitamin E Vitamin C

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201228049866N1**
Registration date: **2021-01-06, 1399/10/17**
Registration timing: **prospective**

Last update: **2021-01-06, 1399/10/17**
Update count: **0**

Registration date
2021-01-06, 1399/10/17

Registrant information

Name
Amir Hossein Doustimotlagh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of hydroalcoholic extract of Nasturtium officinale on level of vitamin C and E, protein carbonyl and inflammatory markers in chronic hemodialysis patients.

Public title
The effect of watercress on hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18 years of age and older Receive hemodialysis at least twice a week for about 3 months Negative history of taking drugs affecting inflammatory markers such as corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs) in a recent month Absence of active infectious diseases, malignant and other obvious inflammatory diseases No history of taking tonics and anti-inflammatory drugs
Exclusion criteria:
Causes unpredictable drug side effects Patients who refused to cooperate and continue the study and received the drug for less than 4 weeks Development of active infectious diseases, cirrhosis and congestive heart failure and malignancy during the study and the need for kidney transplantation Malnutrition and cachexia (body mass index less than 18 kg / m2) Albumin less than 3
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the Restricted randomization method of the randomization Random allocation rule method. For this purpose, first determine a total sample size, then randomly assign a set of them to the intervention group and the rest to the control group.35balls for the intervention group and 35balls for the control group are placed in a lottery container and then the balls are randomly removed from the container without replacement and the created sequence is recorded.
Blinding (investigator's opinion)
Double blinded
Blinding description
Capsules are individually packed envelopes and have an identification number. Capsules and envelopes of Nasturtium officinale extract and placebo are offered in exactly the same appearance and packaging, which will blind the participants and the researcher.
Placebo
Used
Assignment
Parallel
Other design features
Patients undergoing chronic hemodialysis referred to Shahid Beheshti Hospital in Yasouj are randomly divided into two groups (control group and intervention group) with a ratio of 1.1. The amount of 500 mg of hydroalcoholic extract of watercress and placebo is given daily to the intervention and control groups for 4 weeks, respectively. Patients' weight and height were measured by a nurse who was blind to the groups. In serum samples taken at the beginning and end of the dialysis session, serum levels of carbonyl protein, inflammatory markers, and vitamins E and C are determined.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Yasuj University of Medical Sciences
Street address
Saheli Ave., Imam Sajjad Hospital, Yasouj University of Medical Sciences
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591837686
Approval date
2019-11-02, 1398/08/11
Ethics committee reference number
IR.YUMS.REC.1398.112

Health conditions studied

1

Description of health condition studied
Patients undergoing chronic hemodialysis
ICD-10 code
Z49.31
ICD-10 code description
Encounter for adequacy testing for hemodialysis

Primary outcomes

1

Description
Blood urea nitrogen
Timepoint
0-28 days
Method of measurement
Autoanalyzer

2

Description
Triglyceride
Timepoint
0-28 days
Method of measurement
Autoanalyzer

3

Description
Cholestrol
Timepoint
0-28 days
Method of measurement
Autoanalyzer

Secondary outcomes

1

Description
Protein carbonyl
Timepoint
0-28 days
Method of measurement
colorimetric

2

Description
Interleukin 6
Timepoint
0-28 days
Method of measurement
Sandwich Enzyme-Linked ImmunoSorbent Assay

3

Description
Tumor Necrosis Factor Alpha(TNF-α)
Timepoint
0-28 days
Method of measurement
Sandwich Enzyme-Linked ImmunoSorbent Assay

4

Description
Vitamin E
Timepoint
0-28 days
Method of measurement
High-performance liquid

5

Description
Vitamin C
Timepoint
0-28 days
Method of measurement
High-performance liquid

Intervention groups

1

Description
Intervention group: During a four weeks' period, the patients in intervention group take 500 mg hydroalcoholic extract of WC once a day and those in control group receive drug-like (capsule color, packing) containing 500 mg of white flour. Hydroalcoholic extract of WC dose select according to previous clinical and pharmacologic studies. At the end of each week, the patient's drug box control for confounding drugs. The patients check for WC side effects based on the dialysis frequency of at least three times a week. Patients monitor weekly for drug use for the assurance of clinical research, and they ask to bring the empty container.
Category
Treatment - Other

2

Description
Control group: Take a placebo of 500 mg daily for 4 weeks
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Yasouj University of Medical Sciences
Proportion provided by this source
100
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
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available