

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 trial 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 is 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

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

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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. 35 balls for the intervention group and 35 balls 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 committee of Yasuj University of Medical Sciences

Street address

Saheli Ave., Imam Sajjad Hospital, Yasouj University of Medical Sciences

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

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

Cholesterol

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

Mehrdad Bagheri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Marioryad

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Shahid Motahari Blvd., Yasouj University of Medical Sciences, Vice Chancellor for Research and Technology

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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

Yasouj University of Medical Sciences

Full name of responsible person

Amir Hossein Doustimotlagh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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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