

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of hydroalcoholic extracts of *Nasturtium officinale* on antioxidant markers in chronic hemodialysis patients

Protocol summary

Study aim

Determination of the Effect of Hydroalcoholic Extract of *Nasturtium officinale* on Anti-oxidant Markers and Biochemical Markers in Patients Under Chronic Hemodialysis

Design

Randomized, double blind, parallel groups. sample size 54

Settings and conduct

This randomized trial is done in dialysis department of Yasuj Shahid Beheshti Hospital. Patients and clinical caregivers and clinical evaluators are blinded to how the drug is allocated.

Participants/Inclusion and exclusion criteria

1) aged over 18 years 2) Receive hemodialysis at least twice a week, for about 3 months 3) Negative history of using medications with known effect on inflammatory markers such as corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs) in the last month; (4) No active infectious diseases, malignant, rheumatic diseases and other inflammatory diseases

Intervention groups

Patients are divided into 1 to 1 case and control groups (placebo) for 4 weeks.

Main outcome variables

Anti-oxidant Markers, Biochemical Markers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150622022869N7**

Registration date: **2019-08-04, 1398/05/13**

Registration timing: **retrospective**

Last update: **2019-08-04, 1398/05/13**

Update count: **0**

Registration date

2019-08-04, 1398/05/13

Registrant information

Name

Moslem Sedaghattalab

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-25, 1398/04/04

Expected recruitment end date

2019-07-26, 1398/05/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hydroalcoholic extracts of *Nasturtium officinale* on antioxidant markers in chronic hemodialysis patients

Public title

The effect of hydroalcoholic extracts of *Nasturtium officinale* on antioxidant markers in chronic hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged over 18 years; Receive hemodialysis at least twice a week, for about 3 months; Negative history of using medications with known effect on inflammatory markers such as corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs) in the last month; No active infectious diseases, malignant, rheumatic diseases and other inflammatory diseases.

Exclusion criteria:

Patients who require additional supplementary therapies (taking medications that affect the inflammatory process during the study)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Blocks was used for randomization with blocks of the size of 4 that after every 4 patients there was an equal number assigned to each treatment. For each block, one of the arrangements (CCII, CICI, ICCI, IICC, ICIC, CIIC) was randomly chosen (C= Control, I= Intervention). Clinical caregivers and patients are unaware of how to divide and type of drug.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical caregiver and the assessor of the outcome are not aware of groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yasuj University of Medical Sciences

Street address

keshavarzi blvd

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Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2019-06-24, 1398/04/03

Ethics committee reference number

IR.YUMS.REC.1398.037

Health conditions studied**1****Description of health condition studied**

Patients with end stage kidney disease under hemodialysis

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes**1****Description**

Bun, cholesterol, Low Density Lipoprotein, High Density lipoProtein, triglyceride, potassium, albumin, calcium and phosphorus and antioxidant tests including malondialdehyde, glutathione peroxidase, superoxide dismutase, high sensitive-CRP, Total Oxidant capacity, Total Antioxidant capacity, P-SH

Timepoint

At the beginning of the study and 28 days later

Method of measurement

Antioxidant and biochemical tests

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: group receiving the drug, which contains 500 mg of Hydroalcoholic extract of the grass spring daily on dialysis days after dialysis. In order to reduce possible gastrointestinal symptoms, it is advisable to take the medicine with food.

Category

Treatment - Drugs

2**Description**

Control group: includes a 500 mg capsule containing flour with a container that is similar to the drug group in appearance (capsule color, glass size and glass content of the capsule), and the same recommendations are

given to the patients.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shaheed Beheshti Hospital of Yasuj

Full name of responsible person

Moslem Sedaghattalab

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yasuj University of Medical Sciences

Full name of responsible person

Hossein Marie Oriad

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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

Yasuj 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

Moslem sedaghattalab

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

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Person responsible for updating data**Contact**

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

No more information

When the data will become available and for how long

No more information

To whom data/document is available

No more information

Under which criteria data/document could be used

No more information

From where data/document is obtainable

No more information

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

No more information

Comments