Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Iran (Islamic Republic of)

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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

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

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 Lipoproteinn, 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 Sedaghattalalb

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj 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

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

Moslem sedaghattalab

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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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