Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Rhus Coriaria(Sumac) on serum levels of lipids, uric acid and Body Mass Index(BMI) in patients under hemodialysis

Protocol summary

Study aim
Determine the effect of Sumac on serum lipids, uric acid and BMI of hemodialysis patients

Design
A clinical trial with control group was performed on 120 patients undergoing hemodialysis, stratified blocking in a randomized way in three parallel groups, in a phase three clinical trials

Settings and conduct
After obtaining permission from the hospital authorities, by presenting a complete letter of introduction to the patients, based on the criteria for entry and no entry in the dialysis unit of the Shohadaye Ashayer Hospital. After obtaining informed consent, the pre-intervention data were collected in three groups And then the intervention will be done. So that the two groups will receive 2 and 3 grams of Sumac powder and the third group will receive the placebo powder wheat. Common treatments will not be removed. A dietary recall questionnaire and physical activity form are completed before and after the study. The primary and secondary outcome variables are measured and recorded before, sixth and twelfth weeks.

Participants/Inclusion and exclusion criteria
Conditions of entry: The desire to participate in research with informed consent Cure for chronic renal failure according to a doctor's diagnosisy Conditions of No entry:: Any sensitivity and allergy to Sumac and their products Mental disorders

Intervention groups
The two groups are as 2 grams and 3 grams of Sumac, and one as a placebo or control group (wheat flour).

Main outcome variables
Serum levels of lipids (primary outcome) and uric acid and body mass index (secondary outcome) are measured and recorded before the intervention, sixth and twelfth weeks after the intervention.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180407039214N1**
Registration date: **2018-06-19, 1397/03/29**
Registration timing: **prospective**

Last update: **2018-06-19, 1397/03/29**
Update count: **0**

Registration date
2018-06-19, 1397/03/29

Registrant information
Name
Fereshteh Allahnouri
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-07-23, 1397/05/01
Expected recruitment end date
2018-12-22, 1397/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of Rhus Coriaria(Sumac) on serum levels of lipids, uric acid and Body Mass Index(BMI) in patients under hemodialysis

Public title
The effect of Rhus Coriaria on serum levels of lipids
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The age range is 70-35 years Cure for chronic renal failure according to a doctor's diagnosis Start at least three months hemodialysis Do three hemodialysis per week Nephrologist confirmation for patient entry to study Access to the patient 3 months after entering the study The desire to participate in research with informed consent
Exclusion criteria:
Any sensitivity and allergy to Sumac and their products Mental disorders pain and acute illness Excessive weight loss and obesity 40 ≥ BMI ≥ 19 Follow Weight Loss Diets Under Dieticians History of obstructive and inflammatory diseases of the stomach and intestines Severe constipation Pregnancy and lactation Smoking and drinking alcohol Cold Getting more than one lipid-lowering drug (Jim Fiberozyl, etc.) Get a Uric acid-lowering drug Having regular and intense activity
Age
From **35 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified blocks are randomly divided into three groups, while gender, age, and base lipids are matched.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences
Street address
Deputy of Research and Technology of Lorestan University of Medical Sciences, Kamalvand, 5 km Khorramabad - Boroujerd Road
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KhorramAbad
Province
Lorestan
Postal code
381251698
Approval date
2018-03-12, 1396/12/21
Ethics committee reference number
IR.LUMS.REC.1396.399

Health conditions studied

1

Description of health condition studied
hemodialysis
ICD-10 code
Z49.0
ICD-10 code description
Preparatory care for renal dialysis

Primary outcomes

1

Description
serum levels of lipids
Timepoint
Before the intervention, 6 weeks after the intervention and 12 weeks after the intervention
Method of measurement
Laboratory tests

Secondary outcomes

1

Description
uric acid
Timepoint
Before the intervention, 6 weeks after the intervention and 12 weeks after the intervention
Method of measurement
Laboratory tests

2

Description
Body Mass Index
Timepoint
Before the intervention, 6 weeks after the intervention and 12 weeks after the intervention
Method of measurement
By dividing body weight (kg) by height (m * 2)

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Intervention group:
Category
Treatment - Drugs

3

Description
Control group:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Ashayer Hospital
Full name of responsible person
Fereshteh Allahnouri
Street address
Shohada Ashayer Hospital, Enqelab Street, Khorramabad, Lorestan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Dr. Morovvat Taheri Kalani
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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
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Fereshteh Allahnouri
Position
Masters student
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
Associate professor

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Ph.D.

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Nursery

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Person responsible for updating data

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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
Individual data of the participants and the whole potential data are the primary consequences and after the unidentifiable individuals can be shared.

When the data will become available and for how long
6 months after printing results

To whom data/document is available
Academic, scientific, medical, and therapeutic establishments

Under which criteria data/document could be used
For review studies, systematic review and meta-analysis

From where data/document is obtainable
Tahere Toulabi toulabi_t@yahoo.com 00986633120140 00989161613969

What processes are involved for a request to access data/document
After the correspondence and explain the reason for the need for data, the average will be sent after a week's data.

Comments