

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 diagnosis 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3522 8879

Email address

f.alahnoori95@gmail.com

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 $40 \geq \text{BMI} \geq 19$ 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

City

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

City

KhorramAbad

Province

Lorestan

Postal code

4-06633236401

Phone

+98 66 3322 0105

Email

f.alahnoori95@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr. Morovvat Taheri Kalani

Street address

Deputy of Research & Technology of Lorestan
University of Medical Sciences, Kmalalvand, 5 km of
KhorramAbad-Boroujerd Road

City

KhorramAbad

Province

Lorestan

Postal code

381251698

Phone

+98 66 3312 0174

Fax

+98 66 3312 0173

Email

research@lums.ac.ir

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

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Kmalalvand, 5 km
of KhorramAbad-Boroujerd Road

City

KhorramAbad

Province

Lorestan

Postal code

381351698

Phone

+98 66 3312 0140

Fax

+98 66 3312 0140

Email

f.alahnoori95@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences
Full name of responsible person
Tahereh Toulabi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, Kmalalvand, 5 km
of KhorramAbad-Boroujerd Road
City
KhorramAbad
Province
Lorestan
Postal code
381351698
Phone
+98 66 3312 0140
Fax
+98 66 3312 0140
Email
toulabi_t@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Fereshteh Allahnouri
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, Kmalalvand, 5 km
of KhorramAbad-Boroujerd Road
City
KhorramAbad
Province
Lorestan

Postal code
381351698
Phone
+98 663312014
Fax
Email
f.alahnoori95@gmail.com

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