

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

The effect of Nanocurcumin on gene expression of proinflammatory factors in peripheral blood mononuclear cells and serum levels of endothelial function factors in hemodialysis patients

Protocol summary

Study aim

The aim of this study is to determine the effect of nanocurcumin on gene expression of pro-inflammatory factors in peripheral blood mononuclear cells and serum levels of endothelial function factors in hemodialysis patients.

Design

This study is a double-blind clinical trial. 54 patients with inclusion criteria will be allocated to either the curcumin group or the placebo group by blocked randomization method.

Settings and conduct

Among the patients of HD ward in Taleqani Hospital 54 patients will be selected and divided into two groups by blocked randomization method, curcumin group and placebo group. Fasting blood samples will be taken at the beginning of the study and at the end of 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: age of 18-80 years, receiving 4-hour HD treatments 2-3 times per week at least for six months, Exclusion Criteria: Patients with infectious diseases such as hepatitis, Patients with chronic inflammatory diseases, including rheumatoid arthritis and lupus, Use of steroidal and non-steroidal anti-inflammatory drugs, Intake of omega-3 fatty acids and carnitine at least 1 month before the start of the study, Liver disease and thyroid disorders, Planning for kidney transplantation during the study.

Intervention groups

Subjects in the curcumin group received 120 mg curcumin as 3 capsules, each containing 40 curcumin, daily for 12 weeks, whereas the placebo group received 3 corresponding placebo capsules.

Main outcome variables

Gene expression of pro-inflammatory factors (TNF- α , IL-6) and serum levels of endothelial function factors (ICAM-1, VCAM-1)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180328039154N1**

Registration date: **2018-04-25, 1397/02/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-25, 1397/02/05**

Update count: **0**

Registration date

2018-04-25, 1397/02/05

Registrant information

Name

Golchin Vafadar Afshar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3382 0423

Email address

golchin_va@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Nanocurcumin on gene expression of proinflammatory factors in peripheral blood mononuclear cells and serum levels of endothelial function factors in hemodialysis patients

Public title

The effect of Curcumin hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a history of at least 6 months of dialysis
Hemodialysis 2-3 times a week for 4 hours

Exclusion criteria:

Patients with infectious diseases such as hepatitis
Patients with chronic inflammatory diseases, including rheumatoid arthritis and lupus
Use of steroidal and non-steroidal anti-inflammatory drugs
Receive omega-3 fatty acids and carnitine at least 1 month before the start of the study
Liver disease and thyroid disorders
Planning for kidney transplantation during the study
No Patient's tendency to stay in study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through the blocking method. Considering the sample size, each block includes 6 characters and will use AAABBB combination. In the following, all possible modes from the combination will be listed and a code will be allocated to each patient then, 9 codes will be chosen by chance and given to them.

Blinding (investigator's opinion)

Double blinded

Blinding description

A code will be allocated to each patient. Medicine and placebo will be distributed according to those codes by medical team of the dialysis department.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Science and Research Branch, Islamic Azad University

Street address

Science and Research Branch, Islamic Azad University, Shohadaye Hesarak Blvd, Daneshgah Square, Sattari Expy, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۷۸۹۳۸۵۵

Approval date

2016-11-27, 1395/09/07

Ethics committee reference number

IR.IAU.SRB.REC.1395.25

Health conditions studied

1

Description of health condition studied

Hemodialyzed kidney disease patients

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

TNF- α

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Real-Time PCR

2

Description

IL6

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Real-Time PCR

3

Description

ICAM-1

Timepoint

At the beginning of the study and after 12 weeks of

intervention
Method of measurement
Blood test

4

Description
VCAM-1
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 40 mg curcumin three times a day for 12 weeks
Category
Treatment - Other

2

Description
Control group: placebo three times a day for 12 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
گلچین وفادارافشار
Street address
دانشگاه آزاد اسلامی ارومیه
City
Urmia
Province
West Azarbaijan
Postal code
5716814934
Phone
+98 44 3382 0423
Email
Golchin_va@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Fateme Azizabadi Farahani
Street address
Science and Research Branch, Islamic Azad University, Shohadaye Hesarak Blvd, Daneshgah Square, Sattari Expy, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۷۷۸۹۳۸۵۵
Phone
+98 21 4486 5154
Email
f_farahany@yahoo.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Oroumia University of Medical Sciences
Full name of responsible person
Yousef Rasmi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Orjhans Street, Resalat Blvd
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Email
yrasmi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Yousef Rasmi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Orjhans Street, Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

yrasmi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Golchin Vafadar Afshar

Position

Student

Latest degree

Master

Other areas of specialty/work

Biochemistry

Street address

دانشگاه آزاد اسلامی

City

Urmia

Province

West Azarbaijan

Postal code

57168

Phone

+98 44 3275 9180

Email

Golchin_va@yahoo.com

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable