Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation of curcumin effects on Carotid Intima-Media Thickness, pulse-wave velocity and levels of hs-CRP in diabetic patients undergoing hemodialysis

Protocol summary

Study aim

Determining the effect of curcumin on carotid intima-media thickness, pulse-wave velocity and levels of hs-CRP in diabetic patients undergoing hemodialysis

Design

Two arm parallel group randomized trial with control group, double-blind, including 60 patients. randomization is achieved by using computer software.

Settings and conduct

This study will be done on 60 diabetic patients undergoing hemodialysis in Kashan city. Patients will be picked on Nephrology center of Shahid Beheshti hospital (associated with Kashan University of Medical Sciences) based on inclusion criteria. hs-CRP, CIMT and PWV will be measured before and after receiving the medication or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1. diabetic patients undergoing hemodialysis 2. age between 40 to 85 3. GFR Between 15-89 mL/min 4. SBP between 140-160 mmHg and DBP between 90-100 mmHg 5. Not pregnant or lactating 6. Not smoker or alcohol abuser 7. Not having underlying disease including cardiovascular disorders, cancer, autoimmune disorders and hypo or hyperthyroidism 8. not having conditions that cause proteinuria Exclusion criteria : 1. underlying disease that causes admission to hospital . 2. high blood pressure (SBP>160, DBP>100) 3. Not willing to continue 4. using fluvoxamine or any kind of antioxidant drug 5. Night worker

Intervention groups

Curcumin group which receive curcumin (nanocurcumin) 80 g, daily, for 24 weeks . control group which receive placebo .

Main outcome variables

Pulse wave velocity and Carotid intima-media thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200527047584N1**
Registration date: **2020-06-21, 1399/04/01**
Registration timing: **retrospective**

Last update: **2020-06-21, 1399/04/01**
Update count: **0**

Registration date

2020-06-21, 1399/04/01

Registrant information

Name

Hamidreza Talari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

talari_hr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of curcumin effects on Carotid Intima-Media Thickness, pulse-wave velocity and levels of hs-CRP in diabetic patients undergoing hemodialysis

Public title
Evaluation of curcumin effects on vascular disease in diabetic patients undergoing hemodialysis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
GFR Between 15-89 SBP between 140-160 and DBP between 90-100 mmHg Not pregnant or lactating no history of smoking or alcohol abuse no underlying condition including cardiovascular diseases , cancer , autoimmune disorders and thyroid function abnormalities not having underlying disease that causes proteinuria

Exclusion criteria:
underlying diseases that caused admission to hospital High blood pressure using Fluvoxamine or any kind of antioxidant drugs Night worker

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple, Non-probability With use of software

Blinding (investigator's opinion)
Double blinded

Blinding description
Radiologists and technicians who calculate Pulse wave velocity are blind and patients will be referred to them randomly .

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Kashan University of Medical Sciences, Ghotb Ravandi St

City
Kashan

Province
Isfehan

Postal code
8115187159

Approval date
2020-02-17, 1398/11/28

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1398.130

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

2

Description of health condition studied
End stage renal disease

ICD-10 code
N18.6

ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
Carotid-femoral pulse wave velocity

Timepoint
Before intervention and 24 weeks after intervention

Method of measurement
Color doppler ultrasound

2

Description
Carotid Intima-media thickness

Timepoint
Before intervention and 24 weeks after intervention

Method of measurement
Color doppler ultrasound

Secondary outcomes

1

Description
hs-CRP level

Timepoint
before and 24 weeks after intervention
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: receives curcumin 80 mg, daily , for 24 weeks
Category
Treatment - Drugs

2

Description
Control group: receives placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Shahid Beheshti Hospital
Full name of responsible person
Mojtaba Ghasemi Adl
Street address
Shahid Beheshti Hospital, Ghotbe Ravandi Street
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8115187159
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamidreza Banafshe
Street address
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Email
research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Hamidreza Talari
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Radiology
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Postal Code 81151/87159, Shahid Beheshti Hospital, Pezeshk Ave, Ravand Street
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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