Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Effect of curcumin supplementation on serum levels of advanced glycation end products , tumor necrosis factor alpha and metabolic indices in patients with diabetic retinopathy

Protocol summary

Study aim
To determine the effect of curcumin on serum levels of advanced glycation end products, tumor necrosis factor alpha in patients with diabetic retinopathy

Design
Randomized double-blind clinical trial with two arm parallel groups, phase 3 trial

Settings and conduct
The trial will be conducted at outpatient clinic of Nikukari affiliated to Tabriz University of Medical Sciences, Iran. All the patients will be screened by an expert retin for eligibility. Those willing to take part in the study will be carefully evaluated with reference to inclusion criteria. A third party who is blind to the study will give the sequence extracted from allocation software. After an overnight fasting, blood will be collected and curcumin supplements will be provided to the participants. supplementation duration will be 8 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People with diabetic retinopathy Age range 40 to 70 years old Exclusion criteria: Receiving insulin Cases of chronic diseases such as cardiovascular, renal and hepatic disorders malabsorption syndrome and inflammatory bowel disease Having certain physiological conditions like pregnancy and breastfeeding

Intervention groups
Patients in the intervention group will use a curcumin capsule with their lunch, daily. In the control group, patients will use a placebo capsule with their lunch.

Main outcome variables
Advanced Glycation End Products such as Methylglyoxal, Pentosidine, Carboxymehyllysine and Tumor Necrosis Factor Alpha

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121208011689N6**
Registration date: **2018-09-30, 1397/07/08**
Registration timing: **retrospective**

Last update: **2023-08-20, 1402/05/29**
Update count: **1**

Registration date
2018-09-30, 1397/07/08

Registrant information

Name
Sorayya Kheirouri

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2017-08-23, 1396/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of curcumin supplementation on serum levels of advanced glycation end products , tumor necrosis factor alpha and metabolic indices in patients with diabetic retinopathy

Public title
Effect of Curcumin in treatment of diabetic complications
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Desire to cooperate and sign informed consent form after full knowledge of the goals and method of implementation of the study Age between 40 to 70 years old People with diabetic retinopathy without insulin
Exclusion criteria:
Receiving insulin Cases of chronic diseases such as cardiovascular, renal and hepatic disorders Malabsorption syndrome and inflammatory bowel disease (Crohn's disease, celiac sproctomy, short stomach and biliary tract jejuni-ileal syndrome) Having certain physiological conditions like pregnancy and breastfeeding
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The eligible participants will be randomly allocated to intervention and placebo groups using a software generated random blocks. The generated random sequence will be administered by an independent third party who is blind to the trial throughout the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind study, patient and investigator will not be aware of the treatment assignments for the duration of the study. For blinding the trial, the curcumin capsules and placebo, will be identical in appearance, packaging, and labeling. All capsules will be packed and encoded by the company.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sience
Street address
Daneshgah Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5136782465
Approval date
2018-06-11, 1397/03/21
Ethics committee reference number
IR.TBZMED.REC.1397.235

Health conditions studied

1

Description of health condition studied
People with diabetic retinopathy
ICD-10 code
H36.0
ICD-10 code description
Diabetic retinopathy

Primary outcomes

1

Description
Serum level of methylglyoxal
Timepoint
First of study and in the end of study
Method of measurement
Elisa

Secondary outcomes

1

Description
Serum levels of Pentosidine
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Elisa

2

Description
Serum level of Carboxymehtyllyzine
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Elisa

3

Description
Serum level of tumor necrosis factor alpha
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Elisa

Intervention groups

1

Description
Intervention group: Patients in this group will receive curcumin capsule for 8 weeks. curcumin capsule is used once a day with lunch.
Category
Treatment - Drugs

2

Description
Control group:Patients in this group will receive placebo capsules for 8 weeks which are same size and shape and used once a day with lunch.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Nikukari eye hospital
Full name of responsible person
Nima Radkhah
Street address
Daneshgah Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Nima Radkhah
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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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
Not applicable

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

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Part of data about primary consequnece

When the data will become available and for how long
Six month after results published

To whom data/document is available
Researcher who are working in university institutes

Under which criteria data/document could be used
Only for meta-analysis studies data will be available to other researchers.

From where data/document is obtainable
By my gmail n.radkhah@gmail.com

What processes are involved for a request to access data/document
As soon as possible

Comments