Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of curcumin-piperine supplementation on inflammatory, oxidative stress and metabolic indicators in patients with ischemic stroke in the rehabilitation phase: a double-blind clinical trial study

Protocol summary

Study aim

The effects of curcumin-piperine supplementation on inflammatory, oxidative stress and metabolic indicators in patients with ischemic stroke in the rehabilitation phase: a double-blind clinical trial study

Design

Randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

In this study, 60 patients with a stroke referred to the Imam Moosa Sadr Clinic were randomly divided into intervention (Curcumin-piperine 500 mg) and placebo (maltodextrin) according to inclusion and exclusion criteria. , so the researcher did not know the intervention type in addition to the participants themselves. To double-blind this study, all capsules were coded as A and B prior to study initiation, so that the researcher did not know the intervention type addition to the participants themselves.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The person has had a stroke only once, At least 3-6 months have passed since the stroke (sub acute and chronic phase), NIHSS =5-24, diagnosis of stroke by CT-scan and MRI, Age=20-65 years old, BMI=18/5-35, Tendency to participate in the study. Exclusion criteria: Taking anticoagulants such as aspirin, heparin, warfarin, etc. Taking antioxidant and multivitamin supplements and omega-3 supplements.Having malignant diseases and cancers

Intervention groups

Intervention group a daily curcumin-piperine capsule(500 mg curcumin+ 5 mg piperine) and placebo group a daily maltodextrin capsule will receive after meal for 12 weeks.

Main outcome variables

TG; TC; HDL; LDL; Weight; BMI; Waist circumference; Total antioxidant capacity; Fibrinogen; Hs-CRP; BP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N48**
Registration date: **2020-12-18, 1399/09/28**
Registration timing: **prospective**

Last update: **2023-01-11, 1401/10/21**
Update count: **1**

Registration date

2020-12-18, 1399/09/28

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-19, 1399/09/29

Expected recruitment end date

2021-04-18, 1400/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effects of curcumin-piperine supplementation on inflammatory, oxidative stress and metabolic indicators in patients with ischemic stroke in the rehabilitation phase: a double-blind clinical trial study

Public title
Effect of curcumin-piperine in patients with ischemic stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The person has had a stroke only once At least 3-6 months have passed since the stroke (subacute and chronic phase) NIHSS =5-24 diagnosis of stroke by CT-scan and MRI Age=20-65 years old BMI=18/5-35 Tendency to participate in the study

Exclusion criteria:
Taking anticoagulants such as aspirin, heparin, warfarin, etc. Taking antioxidant and multivitamin supplements and omega-3 supplements Having malignant diseases and cancers

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects. Then, within each block, subjects will be randomly assigned to treatment or placebo. Random assignment will be done using a random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to conduct this research in a double-blind manner, before starting the study, the relevant capsules are coded in A and B by a person other than the researcher, so that the researcher does not know the type of capsules received by both participants and researchers.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jerib Avenue

City
Isfahan

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Isfehan

Postal code
8174673461

Approval date
2020-11-18, 1399/08/28

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.593

Health conditions studied

1

Description of health condition studied
Ischemic stroke

ICD-10 code
I63

ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
HS-CRP

Timepoint
The beginning and the end of the study

Method of measurement
ELISA kit

2

Description
TAC

Timepoint
The beginning and the end of the study

Method of measurement
Laboratory method

3

Description
Fibrinogen plasma level

Timepoint

The beginning and the end of the study

Method of measurement

ELISA kit

4

Description

Lipid profile

Timepoint

The beginning and the end of the study

Method of measurement

Enzymatic method

5

Description

Systolic and diastolic blood pressure

Timepoint

The beginning and the end of the study

Method of measurement

Mercury Barometer

Secondary outcomes

1

Description

Weight

Timepoint

The beginning and the end of the study

Method of measurement

Digital scale

2

Description

Waist Circumference (WC)

Timepoint

The beginning and the end of the study

Method of measurement

Inelastic meters

3

Description

Body mass index (BMI)

Timepoint

The beginning and the end of the study

Method of measurement

Dividing the weight into kilograms by squared height by meter

Intervention groups

1

Description

Intervention group: A daily curcumin-piperine capsule(500 mg curcumin + 5 mg piperine) will receive after meal for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: A daily placebo capsule(505 mg maltodextrin) will receive after meal for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Moosa Sadr Clinic

Full name of responsible person

Mohammad Bagherniya

Street address

Imam Moosa Sadr Clinic, Shohada Squre, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Kosar Boshagh

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

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

Title and more details about the data/document
The collected deidentified for the primary outcome measure only will be shared

When the data will become available and for how long
12 months after publication

To whom data/document is available

Researchers and academic and research institutes

Under which criteria data/document could be used

To do similar designs

From where data/document is obtainable

Answer the person

What processes are involved for a request to access data/document

The data will be sent to the person after receiving the request and reviewing the request.

Comments