

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

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 committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

City

Isfahan

Province

Isfahan

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 Squire, Isfahan, Iran
City
Isfahan
Province
Isfahan
Postal code
8135798111
Phone
+98 31 3626 9719
Fax
+98 31 3626 9719
Email
Bagherniya@nutr.mui.ac.ir
Web page address
<http://nutr.mui.ac.ir/>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjou
Street address
Hezar Jarib
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 8138
Fax
Email
sh_haghjoo@med.mui.ac.ir
Web page address
<http://nutr.mui.ac.ir/>
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
Street address
Hezar Jarib
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 21 6553 9905
Fax
Email
kboshagh71@gmail.com
Web page address
<http://nutr.mui.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Bagherniya
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezar Jajrib
City
Isfahan

Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 3154
Fax
+98 31 3668 1378
Email
Bagherniya@nutr.mui.ac.ir

Person responsible for updating data

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
Street address
Hezar Jarib
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 21 6553 9905
Email
kboshagh71@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

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