

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Evaluation of the effect of curcumin-piperine supplement administration on the severity of injury and function in patients with acute ischemic stroke

Protocol summary

Study aim

Investigating the effect of curcumin-piperine supplementation on the severity of acute ischemic stroke based on the NIHSS criteria

Design

This study is a double-blind clinical trial that will be conducted on 68 patients with acute ischemic stroke admitted to the neurology department and who meet the conditions for entering the study.

Settings and conduct

Neurological emergency and neurology department of Ghaem Hospital

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1- Age between 50 and 80 years 2- Less than 24 hours have passed since the start of the stroke. 3- The patient has been diagnosed with an acute ischemic stroke. 4- The GCS of the patient should be more than 13 at the time of the visit. 5- The range of NIHSS is between 5 and 20. 6- MRS should be less than 2 before the onset of stroke. 7- Signing the informed consent form
Criteria for not entering the study: 1- Patients receiving rTPA 2- Candidate patients for endovascular treatment, mechanical thrombectomy, or craniotomy 3- Pregnancy or breastfeeding 4- History of allergy to turmeric or black pepper 5- Taking immunosuppressive drugs 6- Simultaneously receiving any drug or supplement with an antioxidant or anti-inflammatory effect or an approved immune system regulator
Exclusion criteria: 1- Occurrence of severe side effects during the study 2- The patient's unwillingness to continue the study

Intervention groups

34 patients in the curcumin-piperine supplement group, as soon as possible after confirming the diagnosis of acute ischemic stroke, will receive curcumin-piperine tablets at a dose of 500/5 mg twice a day for 4 days along with standard treatment.

Main outcome variables

Injury severity after acute ischemic stroke based on NIHSS Patient performance after acute ischemic stroke based on MRS and BI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201220049774N4**

Registration date: **2022-11-18, 1401/08/27**

Registration timing: **prospective**

Last update: **2022-11-18, 1401/08/27**

Update count: **0**

Registration date

2022-11-18, 1401/08/27

Registrant information

Name

Hesamoddin Hosseinijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1586

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-07, 1401/09/16

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of curcumin-piperine supplement administration on the severity of injury and function in patients with acute ischemic stroke

Public title
Evaluation of the effect of curcumin-piperine supplement in patients with acute ischemic stroke

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 80 years Less than 24 hours have passed since the onset of stroke. The patient has been diagnosed with an acute ischemic stroke. GCS of the patient at the time of visit should be more than 13. The NIHSS range is between 5 and 20. MRS is less than 2 before the onset of stroke. Sign the informed consent form
Exclusion criteria:
Patients receiving rtPA Candidate patients for endovascular treatment, mechanical thrombectomy or craniotomy Pregnancy or breastfeeding History of allergy to turmeric or black pepper Taking immunosuppressive drugs Concomitant receipt of any drug or supplement with an antioxidant or anti-inflammatory effect or an approved immune system regulator

Age
From **50 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Replacement blocks using the site <https://www.sealedenvelope.com> with the explanation that each of the blocks has 4 members and the shape of the blocks can be as follows, for example: [ABAB], [BBAA], [BABA], ... Codes A and B are randomly assigned to intervention and control groups. The site mentioned above randomly selects 17 blocks out of all four possible blocks to include all patients in the study.

Blinding (investigator's opinion)
Triple blinded

Blinding description

In this study, only the DUE unit expert has full knowledge of the type of drug received (placebo or curcumin-piperine supplement) and this person has no role in prescribing, evaluating treatment, and analyzing data. Patients who meet the conditions for entering the study are randomly assigned to one of the groups by the aforementioned expert based on the set codes. Then the pills are placed in the hands of researchers who are unaware of the content of the codes and the type of pills, and they are prescribed. The placebo tablet looks completely similar to the curcumin-piperine tablet and contains the same ingredients except for the active ingredient. Therefore, it is not possible to distinguish pills from each other by patients and clinical caregivers.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Mashhad University of Medical Sciences

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Ferdowsi University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Approval date

2022-07-02, 1401/04/11

Ethics committee reference number

IR.MUMS.REC.1401.084

Health conditions studied

1

Description of health condition studied

Acute ischemic stroke

ICD-10 code

I63.6

ICD-10 code description

Cerebral infarction due to cerebral venous thrombosis, nonpyogenic

Primary outcomes

1

Description

Assessment of stroke severity based on NIH Stroke Scale (NIHSS)

Timepoint

Days 0 and 4 of study

Method of measurement

Questionnaire

2

Description

Evaluation of patients' performance based on Modified Rankin Scale (MRS) and Barthel index (BI)

Timepoint

Days 0, 4 and 30 of the study

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Complete blood count with differential

Timepoint

Once at study entry and again after receiving the last dose of curcumin-piperine

Method of measurement

Laboratory tests

2

Description

Total and direct bilirubin

Timepoint

Once at study entry and again after receiving the last dose of curcumin-piperine

Method of measurement

Laboratory tests

3

Description

C-reactive protein (CRP)

Timepoint

Once at study entry and again after receiving the last dose of curcumin-piperine

Method of measurement

Laboratory tests

4

Description

Hemoglobin A1c (HbA1c)

Timepoint

Once at study entry and again after receiving the last dose of curcumin-piperine

Method of measurement

Laboratory tests

5

Description

Early death

Timepoint

One week and one month after starting the study

Method of measurement

Information about the patient's condition by phone call

Intervention groups

1

Description

Intervention group: 34 patients in the curcumin-piperine supplement group, as soon as possible after confirming the diagnosis of acute ischemic stroke, will receive curcumin-piperine tablets at a dose of 500/5 mg twice a day for 4 days along with standard treatment.

Category

Treatment - Drugs

2

Description

Control group: 34 patients in the control group will receive a placebo pill twice a day for 4 days along with a standard ischemic stroke treatment regimen.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem educational, research and treatment center

Full name of responsible person

Hesamoddin Hosseini

Street address

Qaem Hospital, Dr. Shariati Square, beginning of Ahmadabad Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology

Street address

University Street, next to Hoveyze Cinema, Ghoreishi Building, Deputy of Research and Technology

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Web page address

<https://v-research.mums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Hesamoddin Hosseinjani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

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Position

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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

Undecided - It is not yet known if there will be 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

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