

# 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 Hosseinjani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3180 1586

##### Email address

hosseinjanih@mums.ac.ir

##### 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 Hosseinjani

#### **Street address**

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

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

91766-99199

#### **Phone**

+98 51 3840 0001

#### **Fax**

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#### **Email**

b.ghaem@mums.ac.ir

#### **Web page address**

<https://qaem.mums.ac.ir/>

## **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 Hoveyzeh Cinema, Ghoreshi Building, Deputy of Research and Technology

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 1538

**Fax**

+98 51 3843 0249

**Email**

vcresraech@mums.ac.ir

**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

**Street address**

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

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hesamoddin Hosseinjani

**Position**

Assistant professor

**Latest degree**

Subspecialist

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### Person responsible for updating data

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hesamoddin Hosseinjani

**Position**

Assistant professor

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**Fax****Email**

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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