Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
+98 51 3845 3239
Email
b.ghaem@mums.ac.ir
Web page address
https://quaem.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

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948954

Phone
+98 51 3180 1586

Fax

Email
hosseinjanih@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Hesamoddin Hosseinjani

Position
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Email
hosseinjanih@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Hesamoddin Hosseinjani

Position
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Fax
Email
hosseinjanih@mums.ac.ir

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