

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of the injury severity and organ dysfunction in patients with severe traumatic brain injury receiving the curcumin-piperine supplement

Protocol summary

Study aim

Investigating the effect of curcumin-piperine supplementation on CRP as an index of measured damage in patients with severe traumatic brain injury.

Design

This study is a double-blind clinical trial, with a control group using a placebo, sample size 44 patients, block randomization.

Settings and conduct

Intensive care unit of Shahid Kamyab Hospital, Mashhad

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 70 years; Less than 12 hours have passed since the brain trauma; The diagnosis of severe non-penetrating traumatic brain injury has been made for the patient; The patient's GCS at the time of the visit should be equal to or less than 8; Signing the informed consent form. Exclusion criteria: The impossibility of using nasogastric tube feeding; Patients with severe trauma are candidates for craniotomy surgery; Pregnancy or breastfeeding; History of allergy to turmeric or curcumin product; Simultaneously receiving any drug or supplement with antioxidant or anti-inflammatory effects or approved immune system regulator.

Intervention groups

Intervention group: curcumin-piperine supplement.
Control group: Placebo.

Main outcome variables

C-reactive protein (CRP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201220049774N5**

Registration date: **2022-11-21, 1401/08/30**

Registration timing: **prospective**

Last update: **2022-11-21, 1401/08/30**

Update count: **0**

Registration date

2022-11-21, 1401/08/30

Registrant information

Name

Hesamoddin Hosseinjani

Name of organization / entity

Country

Iran (Islamic Republic of)

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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 injury severity and organ dysfunction in patients with severe traumatic brain injury receiving the curcumin-piperine supplement

Public title

Evaluation of the patients with severe traumatic brain injury receiving the curcumin-piperine supplement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 70 years Less than 12 hours have passed since the brain trauma. The patient has been diagnosed with severe non-penetrating traumatic brain injury. The patient's GCS at the time of visit should be equal to or less than 8. Sign the informed consent form

Exclusion criteria:

The impossibility of using nasogastric tube feeding Patients with severe trauma are candidates for craniotomy surgery Pregnancy or breastfeeding History of allergy to turmeric or curcumin product Concomitant receipt of any drug or supplement with an antioxidant or anti-inflammatory effect or an approved immune system regulator

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

A replacement block 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: [ABAB], [BBAA], [BABA], ... Codes A and B are randomly assigned to intervention and control groups. The site mentioned above randomly selects 11 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 expert of the hospital's drug usage evaluation unit 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

Research and Technology Vice-Chancellor, Qureshi Building, next to Hoize Cinema, University St.

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Razavi Khorasan

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Approval date

2022-06-11, 1401/03/21

Ethics committee reference number

IR.MUMS.REC.1401.098

Health conditions studied**1****Description of health condition studied**

Severe traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes**1****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

Secondary outcomes**1****Description**

Glasgow Coma Scale (GCS)

Timepoint

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

Method of measurement

Clinical test

2

Description

neutrophil-lymphocyte ratio (NLR)

Timepoint

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

Method of measurement

Laboratory test

3

Description

Sequential Organ Failure Assessment (SOFA) Score

Timepoint

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

Method of measurement

Clinical test

Intervention groups

1

Description

Intervention group: 22 patients in the group receiving curcumin-piperine supplement during the first 12 hours after brain trauma will receive curcumin-piperine tablets at a dose of 500/5 mg twice a day for 7 days along with standard treatment.

Category

Treatment - Drugs

2

Description

Control group: 22 patients in the control group will receive a placebo pill twice a day for 7 days along with standard treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational, research and therapeutic center of Shahid Kamyab

Full name of responsible person

Hesamoddin Hosseinjani

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Before Nakhri intersection, Fadaeyan Islam St.

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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

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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

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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Other areas of specialty/work

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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