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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+98 51 3180 1586

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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.

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

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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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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University Street, next to Hoveyzeh Cinema, Ghoreshi Building, 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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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