

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of curcumin-piperine supplement on damage indicators in septic patients admitted to the intensive care unit

Protocol summary

Study aim

The effect of curcumin-piperine supplementation on CRP reduction in patients with sepsis admitted to the intensive care unit

Design

It is a double-blind clinical trial performed on 66 patients with sepsis admitted to the intensive care unit. The permutation block method will be used for randomization and division of patients.

Settings and conduct

Intensive Care Unit of Imam Reza (AS) hospital in Mashhad

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 80 years, sepsis, signing of the informed consent form Exclusion criteria: pregnancy and lactation, history of allergy to turmeric or curcumin product, age less than 18 years, HIV patients, history of organ transplantation, rheumatic disease or active autoimmunity, patients treated with immunosuppressive drugs, patients treated With corticosteroids, radiotherapy, solid tumors or malignancies, white blood cell count less than 1000 μ l, concomitant administration of any drug or supplement with antioxidant or immune regulatory effect, patients without oral/nasal gastrointestinal tract

Intervention groups

33 patients in the intervention group will receive a curcumin-piperine supplement at a dose of 500/5mg twice daily with an antibiotic regimen. 33 patients in the control group will receive a placebo twice a day with an antibiotic regimen.

Main outcome variables

CRP; serum lactate; SOFA score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201220049774N3**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

Registration date

2022-05-14, 1401/02/24

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

2022-05-17, 1401/02/27

Expected recruitment end date

2022-08-08, 1401/05/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of curcumin-piperine supplement on damage indicators in septic patients admitted to the intensive care unit

Public title

Evaluation of the effect of curcumin-piperine supplement in septic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 80 years Having sepsis and being admitted to the intensive care unit Signing an informed consent form

Exclusion criteria:

Pregnancy and lactation History of allergy to turmeric and curcumin products Age under 18 years HIV patients Member transplant history Rheumatic or autoimmune disease Patients treated with immunosuppressive drugs Patients treated with corticosteroids Radiotherapy Solid or malignant tumor Concomitant use of any supplement with antioxidant or anti-inflammatory effect or immune system regulator Patients without oral / nasal gastrointestinal tract White blood cell count less than 1000 / microliter

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted blocks method using the site <https://www.sealedenvelope.com> with the explanation that each block has 6 components. The form of the blocks can be as follows for example: [ABAABAB], [BBABAA], [BABABA], Codes A and B are randomly assigned to intervention and control groups. From all possible six blocks, the site randomly selects 11 blocks to include all the patients in the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the DUE unit expert only has complete information about the type of drug received (placebo or curcumin-piperine supplement). This person plays no role in the administration, treatment evaluation, and data analysis. According to the codes, the patients who fulfill the inclusion criteria are randomly assign to one of the groups by the DUE unit expert. The pills are then given to the researchers who are unaware of the content of the codes and the tablets type, and then prescribed. The placebo pill is very similar in appearance to the curcumin-piperine pill and contains the same ingredients except the active ingredient. Therefore, it is not possible for patients and clinical caregivers to distinguish pills

from each other.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethice Committee of Mashhad University of Medical Sciences

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Approval date

2022-04-09, 1401/01/20

Ethics committee reference number

IR.MUMS.REC.1401.001

Health conditions studied

1

Description of health condition studied

sepsis

ICD-10 code

A41

ICD-10 code description

Other sepsis

Primary outcomes

1

Description

Serum Lactate

Timepoint

At the beginning of the study and after receiving the last dose of curcumin-piperine

Method of measurement

Laboratory tests

2

Description

C-reactive protein (CRP)

Timepoint

At the beginning of the study and after receiving the last

dose of curcumin-piperine
Method of measurement
Laboratory tests

3

Description
SOFA score(Sequential organ failure assessment)
Timepoint
At the beginning of the study and after receiving the last dose of curcumin-piperine
Method of measurement
Laboratory tests

Secondary outcomes

1

Description
Serum creatinine
Timepoint
At the beginning of the study and after receiving the last dose of curcumin-piperine
Method of measurement
Laboratory tests

2

Description
WBC count
Timepoint
At the beginning of the study and after receiving the last dose of curcumin-piperine
Method of measurement
Laboratory tests

3

Description
Platelet count
Timepoint
At the beginning of the study and after receiving the last dose of curcumin-piperine
Method of measurement
Laboratory tests

4

Description
neutrophil to lymphocyte ratio
Timepoint
At the beginning of the study and after receiving the last dose of curcumin-piperine
Method of measurement
Laboratory tests

5

Description
lymphocyte to monocyte ratio
Timepoint
At the beginning of the study and after receiving the last dose of curcumin-piperine

Method of measurement
Laboratory tests

6

Description
platelet to lymphocyte ratio
Timepoint
At the beginning of the study and after receiving the last dose of curcumin-piperine
Method of measurement
Laboratory tests

7

Description
Total Bilirubin
Timepoint
At the beginning of the study and after receiving the last dose of curcumin-piperine
Method of measurement
Laboratory tests

8

Description
Direct Bilirubin
Timepoint
At the beginning of the study and after receiving the last dose of curcumin-piperine
Method of measurement
Laboratory tests

Intervention groups

1

Description
Intervention group: 33 patients will receive curcumin-piperine supplement after diagnosis of sepsis at a dose of 5.500 mg twice daily for 7 days with antibiotic regimen.
Category
Treatment - Drugs

2

Description
Control group: 33 patients will receive placebo twice a day for 7 days with antibiotic regimen
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Hesamoddin Hosseinjani

Street address

Imam reza Education, Research and Treatment
Center, Imam Reza Square, Ibne sina Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Fax

+98 51 3859 1057

Email

IRH@mums.ac.ir

Web page address

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

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 Campus, Azadi Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1586

Email

hosseinjanih@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, nexa 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://vcresraech.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****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

Other areas of specialty/work

Medical Pharmacy

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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

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Latest degree

Subspecialist

Other areas of specialty/work

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Province

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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