

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of curcumin consumption on liver enzyme levels in opium-poisoned patients hospitalized in the Poisoned ICU department

Protocol summary

Study aim

The aim is Investigating the effect of curcumin consumption on liver enzyme levels in opium-poisoned patients hospitalized in the Poisoned ICU department of Loghman Hakim Hospital 2022-2023.

Design

This clinical trial study has two intervention and control groups, double-blind, randomized, with parallel groups, on 30 opium-poisoned patients. Block method will be used for randomization.

Settings and conduct

This clinical trial study has two intervention groups, double-blind, randomized, on 30 opium-poisoned patients and admitted to the intensive care unit at Luqman Hakim Hospital. The patients will be people referred to Luqman Hakim Hospital with opium poisoning in 2022, who have consented to participate and have no other poisoning. Block method will be used for randomization, also in blinding, clinical care and patient companion will be blind. 15 of them are subjected to curcumin gavage and the other 15 are subjected to normal saline gavage.

Participants/Inclusion and exclusion criteria

Patients with opium poisoning, referring to the emergency department of Loghman Hospital in Tehran, who were admitted to the intensive care unit, were included in the study, and patients with simultaneous poisoning with other drugs, the lack of consent of companions to participate in the study and dead cases were excluded from the study.

Intervention groups

Patients in the intervention group will be subjected to curcumin supplemental gavage with a dose of 1500 mg daily for 7 days, manufactured by Dineh Pharmaceutical Company, and in the control group normal saline gavage will be used.

Main outcome variables

Liver enzyme levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220305054196N2**

Registration date: **2023-04-09, 1402/01/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-09, 1402/01/20**

Update count: **0**

Registration date

2023-04-09, 1402/01/20

Registrant information

Name

Mitra Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 4041

Email address

mrahimi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-20, 1401/12/29

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

Investigating the effect of curcumin consumption on liver enzyme levels in opium-poisoned patients hospitalized in the Poisoned ICU department

Public title

Investigating the effect of curcumin on the levels of liver enzymes in opium poisoning

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Opium poisoning Referred to the emergency department of Loghman Hospital in Tehran admitted to the intensive care unit

Exclusion criteria:

Concomitant poisoning with other drugs Lack of consent of companions to participate in the study death of the patient

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of the block randomization type. The size of all the blocks is equal and we will have 6 blocks in this two-group trial, and considering 5 blocks, a total of 30 patients will be evaluated. The randomization tool will be random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the selection of the samples, none of the sampled people will know about the randomization and the process of allocation to the groups, medicine and placebo are completely similar, on this basis and with the patients' lack of information about the group they are in, they have been blinded. Doctors are given a table of coded numbers in advance and patients are entered into the study in the order of the numbers in the table. Therefore, the present study is double-blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Poisoned Complex, Loghman Hakim Hospital, South Kargar St, Tehran

City

Tehran

Province

Tehran

Postal code

1333635445

Approval date

2023-03-12, 1401/12/21

Ethics committee reference number

IR.SBMU.SME.REC.1401.095

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

Poisoning by opium

ICD-10 code

T40.0X4

ICD-10 code description

Poisoning by opium, undetermined

Primary outcomes**1****Description**

Liver enzyme levels

Timepoint

Before treatment and daily up to 7 days after treatment

Method of measurement

Blood sampling is done and the level of liver enzymes is determined using a laboratory kit.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Curcumin supplement gavage, dose 1500 mg daily for 7 days, Dineh Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Control group: Normal saline gavage, with the rate of 1500 mg daily for 7 days, Dina Pharmaceutical Company.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Mitra Rahimi

Street address

Poisoned Complex, Loghman Hakim Hospital, South Kargar St, Tehran

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

loghman.hospital@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hale Talaie

Street address

Toxicological Research Center, Loghman Hakim Hospital, Kamali Ave, South Kargar St, Tehran

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 8175

Email

trc.info@sbm.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Rahimi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Toxicology

Street address

Poisoned Complex, Loghman Hakim Hospital, South Kargar St, Tehran

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

mrahimi744@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Rahimi

Position

Associate Professor

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Postal code

1333635445

Phone

+98 21 5541 9005

Email
mrahimi744@gmail.com

+98 21 5541 9005

Email
mrahimi744@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mitra Rahimi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Toxicology
Street address
Poisoned Complex, Loghman Hakim Hospital, South
Kargar St, Tehran
City
Tehran
Province
Tehran
Postal code
1333635445
Phone

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
Not applicable