

# 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

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##### 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

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##### 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

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## Person responsible for scientific inquiries

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##### Latest degree

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## Person responsible for updating data

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**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