

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of the effects of two drugs, clonidine and dexmethomidine, in the treatment of opiate withdrawal syndrome in patients admitted to the Toxicology ICU of Luqman Hakim Hospital from 2023 to 2025

#### Protocol summary

Symptoms of opium withdrawal syndrome

##### Study aim

The aim are Comparison of the effects of two drugs, clonidine and dexmethomidine, in the treatment of opiate withdrawal syndrome in patients admitted to the Toxicology ICU of Luqman Hakim Hospital from 2023 to 2025.

##### Design

This clinical trial study has two intervention and control groups, unblinded, randomized, with parallel groups, on 52 patients admitted to the intensive care unit with opium withdrawal syndrome. The block method will be used for randomization.

##### Settings and conduct

This clinical trial study has two intervention groups, unblinded, randomized, on 52 patients with opium withdrawal syndrome and admitted to the intensive care unit at Luqman Hakim Hospital. The patients will be cases referring to Luqman Hakim Hospital in the years 2023 to 2025, who are willing to participate and do not have any other diseases. Block method will be used for randomization, 26 cases will be treated with clonidine and 26 cases will be treated with dexmethomidine.

##### Participants/Inclusion and exclusion criteria

Patients with drug addiction, hospitalized in poisoning ICU, with the age of 18 to 75 years, who suffered from withdrawal syndrome during hospitalization, will be included in the study as a study group. Also, if the patient's companion does not agree to participate in the evaluation and contraindications of clonidine or dexmethomidine use, they will be excluded from the study.

##### Intervention groups

The first group will be treated with dexmethomidine at a rate of 0.5 micrograms/kg and the second group will be treated with clonidine up to 1.2 mg per day manufactured by Elixir Pharmaceutical Company.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220305054196N3**

Registration date: **2023-05-18, 1402/02/28**

Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**

Update count: **0**

##### Registration date

2023-05-18, 1402/02/28

##### 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

2023-05-21, 1402/02/31

##### Expected recruitment end date

2023-07-22, 1402/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Comparison of the effects of two drugs, clonidine and dexmethomidine, in the treatment of opiate withdrawal syndrome in patients admitted to the Toxicology ICU of Luqman Hakim Hospital from 2023 to 2025

## Public title

Comparison of the effects of two drugs, clonidine and dexmethomidine, in the treatment of opiate withdrawal syndrome

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with opium addiction Hospitalization in the poisoning ICU With age minimum 18 and maximum 75 years who have suffered withdrawal syndrome during hospitalization

### Exclusion criteria:

Lack of consent of the patient to participate in the evaluation Contraindications to clonidine or dexmethomidine

## Age

From **18 years** old to **75 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **52**

## 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 13 blocks in this two-group trial, and considering 4 blocks, a total of 52 patients will be evaluated. The randomization tool will be random allocation software.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### 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

2023-04-15, 1402/01/26

### Ethics committee reference number

IR.SBMU.RETECH.REC.1402.072

## Health conditions studied

## 1

### Description of health condition studied

Opium withdrawal syndrome

### ICD-10 code

F11.23

### ICD-10 code description

Opioid dependence with withdrawal

## Primary outcomes

## 1

### Description

Symptoms of Opium withdrawal syndrome

### Timepoint

Before drug administration and 12 and 24 hours later

### Method of measurement

Based on COWS checklist criteria

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: In the first group, dexmethomidine drug at the rate of 0.5 micrograms/kg manufactured by Elixir Pharmaceutical Company will be used.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: The second group will be treated with clonidine up to 1.2 mg per day manufactured by Elixir

Pharmaceutical Company .  
**Category**  
Treatment - Drugs

## 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

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**Phone**

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**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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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**

Azade Memarian

**Position**

Resident in toxicology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Toxicology

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## Person responsible for scientific inquiries

#### Contact

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**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Toxicology

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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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available