

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of nebulized naloxone in comparison with intravenous naloxone in patients with methadone overdose, a randomized clinical trial study

#### Protocol summary

##### Study aim

The effect, complications, benefits, and feasibility of administration of nebulized naloxone. The effect, complications, benefits, and feasibility of administration of naloxone infusion. Comparison of effects, complications, benefits, and feasibility of administration of naloxone infusion versus nebulized naloxone.

##### Design

A Phase II randomized clinical trial on 60 patients in which randomization was done using the envelopes containing the name of intervention or control groups.

##### Settings and conduct

All opioid-dependent cases who get poisoned with methadone and responded to the administration of naloxone in the emergency department.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include those methadone overdosed cases >18 and <60 years old who are otherwise safe with no background diseases using methadone as the primary drug and signs of opioid overdose. All patients should be dependent on opioids.

##### Intervention groups

using nebulized naloxone (vs. traditional naloxone infusion) in opioid-dependent patients referred with methadone overdose.

##### Main outcome variables

Intubation; O2 saturation; consciousness level (GCS score); withdrawal syndrome (Cows scale); taking additional doses (rescue dose) of naloxone.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120629010133N4**  
Registration date: **2022-07-07, 1401/04/16**

Registration timing: **prospective**

Last update: **2022-07-07, 1401/04/16**

Update count: **0**

##### Registration date

2022-07-07, 1401/04/16

##### Registrant information

###### Name

Hossein Hassanian-Moghaddam

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5542 4041

###### Email address

hassanian@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-16, 1401/04/25

##### Expected recruitment end date

2023-07-16, 1402/04/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of nebulized naloxone in comparison with intravenous naloxone in patients with methadone overdose, a randomized clinical trial study

##### Public title

Nebulized naloxone in methadone poisoning

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Methadone Overdose >18 and <60 Response to naloxone Opioid dependency Spontaneous respiration

### Exclusion criteria:

No consent to participate nasal congestion Current catching cold Apnea Intubation

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Before starting the project we will write the name "Naloxone infusion" and Nebulized naloxone" on 30 papers each. All papers will be folded and inserted into an envelope and all envelopes will be put in a small box and the head nurse will take it. For randomization after recruitment and assessment of eligibility for inclusion & exclusion criteria and no contraindication for initiation of each treatment, the head nurse will be asked to open the envelopes at random and present them to the physician in charge

## 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

Ethic Committee of Shahid Beheshti University of Medical Sciences

##### Street address

Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717434

## Approval date

2022-06-26, 1401/04/05

## Ethics committee reference number

IR.SBMU.RETECH.REC.1401.162

## Health conditions studied

### 1

#### Description of health condition studied

Opioid, Methadone, Poisoning, naloxone infusion, Nebulized naloxone

#### ICD-10 code

T40.3

#### ICD-10 code description

Poisoning by, adverse effect of and underdosing of methadone

## Primary outcomes

### 1

#### Description

O2 Saturation

#### Timepoint

On admission, then each hour till 6 hours, then each 3 hours

#### Method of measurement

Pulse oxymetry

### 2

#### Description

pCo2

#### Timepoint

On admission, then each hour till 6 hours, then each 3 hours

#### Method of measurement

Blood gasometry

### 3

#### Description

Level of consciousness using Glasgow Coma Scale

#### Timepoint

On admission, then each hour till 6 hours, then each 3 hours

#### Method of measurement

Physical Examination

## Secondary outcomes

### 1

#### Description

Withdrawal Syndrome using COWS scale

#### Timepoint

Each 3 hours

#### Method of measurement

Examination

## Intervention groups

### 1

#### Description

Intervention group: naloxone administration by jet nebulizer, using 2/3 of i.v. naloxone in emergency department to avoid re-narcosis

#### Category

Treatment - Drugs

### 2

#### Description

Control group: naloxone administration by pump infusion or serum set, using 2/3 of i.v. naloxone in emergency department to avoid re-narcosis

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Loghman Hakim Hospital

##### Full name of responsible person

Hossein Hassanian-Moghaddam

##### Street address

Kamali Avenue, South Karegar

##### City

Tehran

##### Province

Tehran

##### Postal code

1333625445

##### Phone

+98 21 5540 9534

##### Email

hassanian@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

Vice chancellor of research, Arabi St, Velenjak, Yaman street

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

##### Phone

+98 21 2243 9780

##### Fax

+98 21 2243 9780

##### Email

zarghi@sbmu.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

Abbas Edalatkhah

##### Position

Emergency medicine Specialist and registrar for clinical toxicology

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Emergency Medicine

##### Street address

Loghman Hakim Hospital, Kamali Ave, South Karegar

##### City

Tehran

##### Province

Tehran

##### Postal code

1333625445

##### Phone

+98 21 5540 9534

##### Email

abbas\_edalatkhah@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Hossein hassanian-Moghaddam

##### Position

Associate professor

##### Latest degree

Medical doctor

**Other areas of specialty/work**

Toxicology

**Street address**

Loghman Hakim Hospital, Kamali Ave, South Karegar

**City**

Tehran

**Province**

Tehran

**Postal code**

دانشیار

**Phone**

+98 21 5540 9534

**Email**

hassanian@sbm.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Abbas Edalatkhah

**Position**Emergency medicine Specialist and registrar in  
Clinical Toxicology**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

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Loghman Hakim Hospital, Kamali Ave, South Karegar

**City**

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**Postal code**

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**Phone**

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**Email**

abbas\_edalatkhah@yahoo.com

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

We will share the data after decoding if there was a reasonable request

**When the data will become available and for how long**

6 month after publication, if SBMU accept sharing

**To whom data/document is available**

Only academics

**Under which criteria data/document could be used**

Not decided yet

**From where data/document is obtainable**

The corresponding author of the published article

**What processes are involved for a request to access data/document**

The type of requested data should be defined and we will try to respond to the queries within one month

**Comments**