

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison effects of two methods of naloxone administration on improvement of clinical manifestations in patients with opium toxicity.

#### Protocol summary

##### Study aim

Comparison effect of two methods of naloxone administration on improvement of clinical manifestation in patients with opium toxicity.

##### Design

Clinical controlled trial with parallel design will perform on 60 patients with known opium toxicity referred to hospital emergency. Patients with spontaneous breathing more than 6 breaths per minute, without unstable hemodynamic and nose bleeding will be assigned in two groups with randomized block design. In intervention group naloxone is administered using a nebulizer and in control group naloxone is administered intravenously. Changes in vital signs, consciousness and saturation of oxygen are evaluated in two groups.

##### Settings and conduct

This study is performed in the emergency department of Loghman Hospital in Tehran. This study was performed under the supervision of an emergency medicine. Patients and individuals who measure clinical changes are unaware of the type of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Known opium toxicity; age more than 15 years; spontaneous breathing more than 6 breathes per minute. Exclusion criteria: Naloxone allergy, Nose bleeding; unstable hemodynamic.

##### Intervention groups

Intervention group: Administration of naloxone using nebulizer oxygen mask at dose of 2 mg diluted in 3 ml normal saline. Control group: Administration of intravenous naloxone at dose of 0.04 mg diluted in 5 ml normal saline.

##### Main outcome variables

Blood pressure, Respiratory rate, Heart rate, Arterial oxygen saturation, Level of consciousness, Clinical opiate withdrawal scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110514006481N14**

Registration date: **2020-11-28, 1399/09/08**

Registration timing: **prospective**

Last update: **2020-11-28, 1399/09/08**

Update count: **0**

##### Registration date

2020-11-28, 1399/09/08

##### Registrant information

##### Name

Mohsen Soleimani

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4190

##### Email address

soli257@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2021-12-22, 1400/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison effects of two methods of naloxone administration on improvement of clinical manifestations in patients with opium toxicity.

## Public title

Comparison of two methods of naloxone administration on improvement of clinical manifestations in patients with opium poisoning.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Known opium toxicity Spontaneous breathing more than 6 breath per minute Age above 15 years old

### Exclusion criteria:

Nose bleeding Unstable hemodynamic Allergy to naloxone

## Age

From 15 years old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization is done using stratified permuted block randomization. Patients are divided into two strata of male and female. For each stratum, a separate random assignment continues to reach the sample size. For random assignment in each stratum, four blocks of (A, B), which include different states of test and control sequences (AABB, ABAB ...), are used. Block selection and randomization is done with website (URL: <https://www.sealedenvelope.com>).

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Because all patients receive oxygen with mask, patients and individuals evaluating response to treatment are unaware of the type of intervention received. But emergency physician, nurses, and researchers are aware of the type of intervention.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Semnan University Of Medical Sciences

##### Street address

Semnan university of medical sciences, Shahid Akhlaghi intersection, Basij Blvd., Semnan, Iran.

##### City

Semnan

##### Province

Semnan

##### Postal code

3514799442

##### Approval date

2020-09-22, 1399/07/01

##### Ethics committee reference number

IR.SEMUMS.REC.1399.185

## Health conditions studied

### 1

#### Description of health condition studied

Opioid dependence

#### ICD-10 code

F11.22

#### ICD-10 code description

Opioid dependence with intoxication

## Primary outcomes

### 1

#### Description

Level of consciousness

#### Timepoint

5 min, 10 min, 15 min and 20 min after naloxone administration

#### Method of measurement

Glasgow Coma Scale

### 2

#### Description

Vital signs

#### Timepoint

5 min, 10 min and 20 min after naloxone administration

#### Method of measurement

Ward monitor

### 3

#### Description

Clinical opiate withdrawal signs

#### Timepoint

5 min, 10 min and 20 min after naloxone administration

#### Method of measurement

Clinical Opiate Withdrawal Scale (COWS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Administration of naloxone hydrochloride (Tolidaru Pharmaceutical Co, Tehran, Iran) at dose of 2 mg with nebulizer mask that diluted in 3 ml normal saline.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Naloxone hydrochloride (Tolidaru Pharmaceutical Co, Tehran, Iran) administration intravenously at dose of 0.04 mg diluted in 4 ml normal saline.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Loghman hospital

##### Full name of responsible person

Fatemeh Keshavarz

##### Street address

Loghman hospital, south kargar street, Tehran, Iran.

##### City

Semnan

##### Province

Semnan

##### Postal code

21 5541 9005

##### Phone

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##### Email

Soli257@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Semnan University of Medical Sciences

##### Full name of responsible person

Parviz Kokhaei

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Semnan university of medical sciences, Shahid Akhlaghi intersection, Basij Blvd., Semnan, Iran.

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#### Phone

+98 23 3365 4190

#### Email

Soli257@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Semnan University of Medical Sciences

#### Proportion provided by this source

1

#### 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

Semnan University of Medical Sciences

##### Full name of responsible person

Mohsen Soleimani

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Nursing faculty, Semnan University of Medical Sciences, 5th Km of Damghan Road

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Nasim Zamani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Department of emergency, Loghman hospital, south of kargar street, Tehran.

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Tehran

**Province**

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1333625445

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

Semnan University of Medical Sciences

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**Phone**

0098 23 3354190

**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available