

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Intranasal versus intravenous administration of naloxone in pediatric opioid poisoned patients, A pilot randomized clinical trial

#### Protocol summary

##### Study aim

Measurement and evaluation of the clinical response (return of spontaneous respiration within 3 minutes of naloxone administration) to a new nasal naloxone formulation in opioid poisonings in the pediatric Emergency Department.

##### Design

Clinical randomized, non-inferiority, parallel-group, phase 1-2 trial on 40 patients. Randomization was centralized and computerized with concealed randomization sequences carried out at an external website.

##### Settings and conduct

The pediatrics department of Loghman-Hakim Hospital Poison Center is the only center for pediatric toxicology in Tehran (Iran). In this trial, 40 opioid poisoned patients were randomized 1:1 to receive naloxone hydrochloride, either intranasally (1.4mg/0.1ml) or IV (0.8 mg) with escalating dose of 0.1 mg/kg naloxone hydrochloride IV if it doesn't respond). Supportive care or oxygenation will be administered simultaneously in accordance with existing clinical protocol. Due to the nature of the study blinding was not possible.

##### Participants/Inclusion and exclusion criteria

All pediatric opioid-poisoned patients who were referred with clinical and laboratory confirmation of opioid poisoning, and did not take the antidote and had no IV line access.

##### Intervention groups

Opioid-poisoned children were randomized 1:1 to receive naloxone hydrochloride, either intranasally (1.4mg/0.1ml) or IV (0.8 mg) with an escalating dose of 0.1 mg/kg naloxone hydrochloride IV if it doesn't respond). and underwent under close monitoring.

##### Main outcome variables

The proportion of patients with a return of spontaneous respiration (above the minimum respiratory rate in each age group per minute) within 3 minutes of naloxone administration would be the primary outcome.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120629010133N7**

Registration date: **2023-06-06, 1402/03/16**

Registration timing: **retrospective**

Last update: **2023-06-06, 1402/03/16**

Update count: **0**

##### Registration date

2023-06-06, 1402/03/16

##### 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

2021-01-16, 1399/10/27

##### Expected recruitment end date

2023-04-16, 1402/01/27

##### Actual recruitment start date

2023-04-16, 1402/01/27

##### Actual recruitment end date

2023-04-16, 1402/01/27

##### Trial completion date

2023-04-16, 1402/01/27

## Scientific title

Intranasal versus intravenous administration of naloxone in pediatric opioid poisoned patients, A pilot randomized clinical trial

## Public title

The efficacy of intranasal naloxone in pediatric opioid overdose patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age more than 1 and less than 12 Opioid poisoning  
Respiratory depression Miotic pupils Unarousable as defined by Glasgow Coma Score (GCS)  $\leq$  12/15

### Exclusion criteria:

Still conscious on ED arrival time Patients that have received naloxone in any form in the previous 24 hours  
Referral cases with unknown drug intervention Patients who have been referred with IV access Presentation with apnea Nasal congestion No parental deferred consent provided GCS  $<$  7/15 History of drug hypersensitivity relevant to naloxone Co-ingestion of other drugs  
Intubation before recruitment major facial trauma Epistaxis Negative urine screening test for opioids A clinical condition (such as abnormal liver function; respiratory, renal or cardiac issues) which, in the opinion of the examining medical practitioner, makes participation in the study inappropriate.

## Age

From **1 year** old to **12 years** old

## Gender

Both

## Phase

1-2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

Actual sample size reached: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The allocation sequence was generated in one session by the PI (who was not involved in treating patients) through a random digit generator website, and the PI stored the randomization list in a locked cabinet.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

### Assignment

Parallel

## Other design features

## Secondary Ids

### 1

#### Registry name

WHO Universal Trial Number

## Secondary trial Id

U1111-1260-5747

## Registration date

2020-11-02, 1399/08/12

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Buiding no 2, Shahid Beheshti University of medical Sciences, Arabi St, Yaman St, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2021-06-13, 1400/03/23

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1400.162

## Health conditions studied

### 1

#### Description of health condition studied

Overdose, opioids, Children, Antidote, Naloxone, Intranasal

#### ICD-10 code

T40

#### ICD-10 code description

Poisoning by narcotics and psychodysleptics [hallucinogens]

## Primary outcomes

### 1

#### Description

Proportion of patients with return of spontaneous respiration (above minimum respiratory rate in each age group per minute)

#### Timepoint

On arrival and within 3 minutes of naloxone administration, then each 4 hours

#### Method of measurement

Measuring the number of respiration in a minute

## Secondary outcomes

### 1

#### Description

Time it takes to place IV cannula

#### Timepoint

From start of procedure till the end (ready for intravenous use)

**Method of measurement**

Measured by stopwatch (per second)

**2**

**Description**

Level of consciousness

**Timepoint**

Before intervention, 3 minute after intervention, then each 4--hour

**Method of measurement**

Using Glasgow Coma Scale

**3**

**Description**

O2 saturation before and after naloxone administration

**Timepoint**

Before intervention, 3 minute after intervention, then each 4--hour

**Method of measurement**

Using pulse oxymeter

**4**

**Description**

Increased pCO2

**Timepoint**

Before intervention, 3 minute after intervention, then each 4--hour

**Method of measurement**

Using blood gas machine

**5**

**Description**

Need for a rescue opioid antidote in ED and afterward

**Timepoint**

During ED admission or afterward till discharge

**Method of measurement**

Record each dose naloxone, route of administration and time given during admission

**Intervention groups**

**1**

**Description**

Intervention group:

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Loghman Hakim Hospital

**Full name of responsible person**

Narges Gholami

**Street address**

Kamali Ave, Sout Karegar Street

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

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Building no 2, Arabi St, Yaman St

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**Grant name**

Comparison of intranasal versus intravenous administration of naloxone in improvement of loss of conscious, respiratory rate and oxygen saturation in pediatric opioid poisoned patients, A pilot randomized clinical trial

**Grant code / Reference number**

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

No

**Title of funding source**

DNE pharma

**Proportion provided by this source**

20

**Public or private sector**

Private

**Domestic or foreign origin**

Foreign

**Category of foreign source of funding**

Sponsor: country of origin

**Country of origin**

NO

**Type of organization providing the funding**

Industry

## Person responsible for general 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**  
Subspecialist

**Other areas of specialty/work**  
Addiction Medicine,

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Narges Gholami

### Position

Associate Professor

### Latest degree

Specialist

### Other areas of specialty/work

Pediatrics

### Street address

Pediatric ward, Loghman Hakim Hospital, Kamali Ave, south karegar, tehran

### City

Tehran

### Province

Tehran

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1333635445

### Phone

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### Email

nargesgholami724@yahoo.com

## 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 further information

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is 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

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

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

Part of the collected deidentified IPD for the primary outcome measure only

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

There is no further information

### To whom data/document is available

Only available for people working in academic institutions

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

Only by written request and subject to considering the right of authors

### From where data/document is obtainable

By email to the corresponding author

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

Determination of exact data and an explanation for possible contribution

### Comments