Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 tow 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 administrated using a nebulizer and in control group naloxone is administrated intravenously. Changes in vital sings, 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, Arteria 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

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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
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Semnan university of medical sciences, Shahid Akhlaghi intersection, Basij Blvd.,Semnan, Iran.
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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
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Sponsors / Funding sources

1

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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

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Person responsible for updating data

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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