Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Intranasal versus Intravenous Naloxone in opium poisoning in children.

Protocol summary

Study aim
Efficacy of Intra nasal naloxone on respiratory rate,consciousness and O2Saturation in opium poisoning in children

Design
Patients with inclusion criteria divided into 2 groups alternately; Intra nasal naloxone dribbling(case) group and Intra venous naloxone injection(control) group . There is no randomization.

Settings and conduct
Patients 1-13 years-old with opium poisoning referred to Loghman-Hakim hospital poison center treated with Intranasal naloxone dribbling in one patient and Intravenous naloxone injection in the next one .

Participants/Inclusion and exclusion criteria
One year to 13 years Opium poisoning No nasal congestion Parental agreement No history of Cardiopulmonary arrest,Coma,Apnea.

Intervention groups
Intranasal naloxone dribbling for patients as case group and Intravenous Naloxone injection for the next one as control group.

Main outcome variables
Respiratory Rate;O2 Saturation;Level of conscienceness(Glasgow Coma Scale) GCS.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180226038869N1**
Registration date: **2019-02-22, 1397/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**
Update count: **0**

Registration date
2019-02-22, 1397/12/03

Registrant information

Name
Fariba Farnaghi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 5102 5000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Intranasal versus Intravenous Naloxone in opium poisoning in children.

Public title
Intranasal naloxone for treatment of opioid poisoning in children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Opium poisoning 1-13 years No nasal congestion Parental agreement

Exclusion criteria:

Age
From **1 year** old to **13 years** old

Gender

Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Lack of enough evidence for IN naloxone in treatment of opiod poisoning in children

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Loghman-Hakim Hospital,Kamali St.,South Kargar Ave
City
Tehran
Province
Tehran
Postal code
1333635445
Approval date
2018-06-17, 1397/03/27
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.258

Health conditions studied

1

Description of health condition studied
Pediatrics Poisoning
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Respiratory Rate in one minute and register in questionnaire .
Timepoint
Before and after intervention every minute till clinical response.
Method of measurement
Physician Observation

2

Description
Level of conscious
Timepoint
Before and after intervention every minute till recovery
Method of measurement
Physician Observation with Glascow coma scale

3

Description
O2 Saturation
Timepoint
Before and after intervention every minute till recovery
Method of measurement
Pulse oximetery

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dribbling of intra nasal Naloxone 0.01mg/kg
Category
Treatment - Drugs

2

Description
Control group: Intravenous injection of Naloxone 0.01mg/kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman-Hakim Hospital
Full name of responsible person
Fariba Farnaghi
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Sponsors / Funding sources

1

Sponsor
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Shahid Beheshti University of Medical Sciences
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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
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
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Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Toxicology
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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
Patient Privacy
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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Medical Journal
When the data will become available and for how long
2019
To whom data/document is available
Medical Doctor Academic researcher
Under which criteria data/document could be used
Future resherches
From where data/document is obtainable
E-mail
What processes are involved for a request to access data/document
E-mail
Comments