Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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) ≤ 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 Behehsti University of Medical Sciences
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Buiding no 2, Shahid Beheshti University of medical Sciences, Arabi St, Yaman St, Tehran
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Tehran
Province
Tehran
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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 Glascow 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

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Kamali Ave, Sout Karegar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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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