

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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)

Phone

+98 21 5102 5000

Email address

faribafarnaghi@yahoo.com

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 opioid 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 Glasgow coma scale

3

Description

O2 Saturation

Timepoint

Before and after intervention every minute till recovery

Method of measurement

Pulse oximetry

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

Street address

Loghman-Hakim Hospital. Kamli st. South Kargar Ave.

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Street address

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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

Fariba Farnaghi

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Toxicology

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Person responsible for scientific 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

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