Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two different regimens of naloxone in treatment of methadone-overdosed addicted patients

Protocol summary

Summary

The main aim is to determine the best dose of naloxone in reversal of the signs and symptoms of methadone overdose in opium-addicted patients.In this phase 2 study in Loghman Hakim hospital, patients will randomly be assigned into either intervention or control group. The 50 patients in the intervention group receive naloxone with dose of 0.04 mg increasing to 0.4- 2, and 10 mg if not responding (Goldfrank Method). The 50 patients in the control group receive naloxone with dose 0.1 mg repeated every 3 minutes until reversal of the signs and symptoms of toxicity (Tintinalli Method). The patients will then be compared regarding the reversal of the overdose signs and symptoms and the time needed for that and occurrence of withdrawal signs and symptoms to determine the preferred method. Only the patients are blind to the dose of naloxone administered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041710133N2**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-29, 1395/03/09

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
Toxicological Research Center-Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two different regimens of naloxone in treatment of methadone-overdosed addicted patients

Public title

Comparison of two different regimens of naloxone in treatment of methadone-overdosed addicted patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Addicted methadone-overdosed patients referring; Positive signs and symptoms of methadone overdose (miosis/respiratory depression/loss of consciousness) Exclusion Criteria: Age younger than 12 years and older than 65 years; previous history of cardiovascular disease; history of respiratory complications due to naloxone; emergent situation that mandates immediate intubation

Age

From **12 years** old to **65 years** old

Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Behesti University of Medical Sciences
Street address
Yaman St, Velenjak
City
Tehran
Postal code
198396-3113
Approval date
2016-02-07, 1394/11/18
Ethics committee reference number
IR.SBMU.RAM.REC.1394.530

Health conditions studied

1

Description of health condition studied
Opioid Poisoning
ICD-10 code
T40
ICD-10 code description
T40

Primary outcomes

1

Description
reversal of respiratory depression
Timepoint
every 3-5 minutes until reversal of the overdose signs and symptoms
Method of measurement
Check vital signs and VBG

Secondary outcomes

1

Description
occurence of withdrawal syndrome
Timepoint
every 5 to 10 minutes
Method of measurement
check of withdrawal signs and symptoms

Intervention groups

1

Description
In the intervention group: administration of naloxone (Tolid Daru Company) with the initial dose of 0.04 mg increasing to 0.4- 2, and 10 mg
Category
Treatment - Drugs

2

Description
In the control group: administration of naloxone (Tolid Daru Company) with the dose 0.1 mg every 3 minutes to reverse the signs and symptoms of methadone overdose
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Hossein Hassanian-Moghaddam
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Toxicological Research Center-Ṡhahid Beheshti University of Medical Sciences-Vice Chancellor for Re
Full name of responsible person
Dr Arezou Mahdavinejad
Street address
Toxicological Research Center- Loghman Hakim Hospital
City
Tehran

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Toxicological Research Center-Ṡhahid Beheshti University of Medical Sciences-Vice Chancellor for Re

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Poisoning Ward-Loghman Hakim Hospital
Full name of responsible person
Dr Navid Khosravi
Position
Fellowship of clinical toxicology
Other areas of specialty/work
Street address
Loghman Hakim Hospital
City
Tehran
Postal code
Phone
+98 21 5541 9005
Fax
Email
khosravi.navid@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Clinical Toxicology
Full name of responsible person
Dr Hossein Hassanian-Moghaddam
Position
Assistant Professor
Other areas of specialty/work
Street address
Loghman Hakim Hospital
City
Tehran
Postal code
Phone
+98 21 5541 9005
Fax
Email
hasanian2000@yahoo.com, hassanian@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Loghman Hakim Poisoning Ward
Full name of responsible person
Dr Navid Khosravi
Position
Fellowship of Clinical Toxicology
Other areas of specialty/work
Street address
Loghman Hakim Hospital
City
Tehran
Postal code
Phone
+98 21 5542 4041
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty