Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of intramuscular naloxone in comparison with intravenous naloxone inpatients with methadone overdose, a randomized clinical trial study

Protocol summary

Study aim
Determination of effects, complications, benefits, and feasibility of intramuscular naloxone

Design
Randomised (with the parallel control group), superiority, single-blinded trial. Randomisation will carry out at two different centers. The intervention group is Intramuscular naloxone and the control group is naloxone infusion which will be selected based on convenience sampling. The sample size is calculated based on a pilot study on 15 patients in each group, showing apnea/re-narcosis in 20% calculating with a power of 80%. alpha=5%, 199 cases in each group.

Settings and conduct
All the patients in the two centers of Tehran and Gorgan will be recruited to take Intramuscular or intravenous naloxone. Except for the study analyzer, all other people are not blinded to the study due to injection issues (one-sided blinded). Both groups will take intravenous naloxone and for maintenance treatment, they will get either 2/3 of the initial bolus dose i.v. hourly or they will get intramuscular injections every 4 hours in the following groups: 0.4, 0.8, 1.2, or 1.6 mg.

Participants/Inclusion and exclusion criteria
Inclusion criteria: methadone overdose as the main drug, age over 18 and under 60, no background diseases, complete response to naloxone, opioid dependant

Intervention groups
Intramuscular injection of naloxone in the case group and intravascular infusion of naloxone in the case group. The variables of the study will be evaluated through the differences between the two routes of naloxone injection interventions.

Main outcome variables
Re-narcosis; Withdrawal Syndrome; Intubation; Hospital Stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120629010133N6**
Registration date: **2023-01-01, 1401/10/11**
Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**
Update count: **0**

Registration date
2023-01-01, 1401/10/11

Registrant information

Name
Hossein Hassanian-Moghaddam

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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+98 21 5542 4041

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-20, 1401/10/30

Expected recruitment end date
2024-01-20, 1402/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of intramuscular naloxone in comparison with intravenous naloxone inpatients with methadone overdose, a randomized clinical trial study

Public title
Intramuscular Naloxone in methadone overdose
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
methadone overdose as the main substance age>=18 age<=60 no background diseases response to naloxone in initial try opioid dependent
Exclusion criteria:
no informed consent
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **398**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Only data analyzer is not aware of the groups. Patients, assessors, physicians, and nurses are aware of the route of administration (IM vs. IV)
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
5th floor, bulding no 2, Shahid Aarabi St, Yaman St.
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-12-04, 1401/09/13
Ethics committee reference number
IR.SBMU.RETECH.REC.1401.580

Health conditions studied

1

Description of health condition studied
methadone
ICD-10 code
T40.3
ICD-10 code description
Poisoning by, adverse effect of and underdosing of methadone

Primary outcomes

1

Description
Renarcosis
Timepoint
On-arrival blood gas analysis and then each 4 hours
Method of measurement
Blood gas

2

Description
Withdrawal syndrome
Timepoint
On-arrival band then each 4 hours
Method of measurement
Evaluation of COWS scale

3

Description
Need for naloxone
Timepoint
Each hour
Method of measurement
Blood gasometery, reduced respiratory rate, Apnea

4

Description
Need for intubation
Timepoint
hourly
Method of measurement
Clinical and laboratory indications for intubation

Secondary outcomes

1

Description

Hospitalization period
Timepoint
End of hospitalization
Method of measurement
Days of hospitalization

Intervention groups

1

Description
Intervention group: Intramuscular injection of naloxone would be calculated every 4 hours based on the calculation for I.V. naloxone: If the calculated dose is less than 0.2 mg/h, then naloxone IM would be 0.4 mg every 4 hours. if the calculated amount is between 0.2-<0.4, then naloxone IM would be 0.8 mg every 4 hours. if the calculated dose is between 0.4-<0.6, then naloxone IM would be 1.2 mg every 4 hours. For amounts above 0.6 mg, the IM dose would be 1.6 mg every 4 hours.
Category
Treatment - Drugs

2

Description
Control group: The routine treatment of methadone poisoning including I.V. naloxone infusion, in which it would be 2/3 of the response dose in the emergency department every hour.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghaman Hakim Hospital
Full name of responsible person
Ali Jangjou
Street address
Kamali Ave, South Karegar
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2

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
5th floor, bulding no 2, Yaman St
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Grant name
Grant code / Reference number
32908
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
Hossein Hassanian-Moghaddam
Position

Assiciate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Toxicology

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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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