

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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@sbm.u.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

occurrence 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-Şahid 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-Şahid 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

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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

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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