

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of oral naltrexone to maintain normal ventilation after acute methadone Poisoning in Opioid non-dependent Patients

Protocol summary

Summary

The aim of this research is assessment of clinical role of oral naltrexone in prevention of respiratory depression and maintenance of normal ventilation and also prevention of loss of consciousness and its' complication like aspiration pneumonia in non-opioid dependent patients with acute pure Methadone toxicity (long-acting opioid) who comes to toxicology emergency department at Lohman hospital, by prescription of 50 mg Naltrexone via gastrointestinal tract (oral). Addicted patients, active liver disease, and patient with recent history of acute coronary syndrome will be excluded from research. After initial standard emergent management non-opioid dependent patients with pure acute methadone toxicity with double blind randomization will divide to 2 groups (intervention and control group). Patients in intervention group will take single dose of 50 mg naltrexone. Both group will admit to ward at least for 48 hours and under go respiratory monitoring by physical examination, inspection, oxygen saturation monitoring with pulseoxymetry, and ventilation by checking arterial blood gas at the ward. At the end the respiratory status and the need for Naloxone prescription and hospital stay will compare between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012062910133N1**

Registration date: **2013-03-22, 1392/01/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-22, 1392/01/02

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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+98 21 5542 4041

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Recruitment status

Recruitment complete

Funding source

Toxicological research Center/Lohman-Hakim Hospital
Poison Center

Expected recruitment start date

2012-11-20, 1391/08/30

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of oral naltrexone to maintain normal ventilation after acute methadone Poisoning in Opioid non-dependent Patients

Public title

The role of naltrexone in opioid toxicity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The acutely methadone-poisoned patients ;opioid non-dependent patients; Exclusion criteria: The addicted patients (Opioid-dependent

patients); Active liver disease; Acute methadone poisoning with development of complications (aspiration pneumonia, brain trauma, and cardiogenic or non-cardiogenic pulmonary edema); History of acute coronary syndrome in last 3 weeks

Age

From **14 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti Medical University

Street address

Velenjak, Next to Taleghani Hospital

City

Tehran

Postal code

Approval date

2012-09-16, 1391/06/26

Ethics committee reference number

122

Health conditions studied

1

Description of health condition studied

Acute Opioids Toxicity

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

Oxygenation (Arterial Blood Oxygen Saturation in Percent)

Timepoint

Continuously up to 48 hours

Method of measurement

Pulseoxymetry

2

Description

Ventilation status

Timepoint

every 6 hours up to 48 hours

Method of measurement

Arterial or venous blood gas

3

Description

Hospital Stay

Timepoint

Hours

Method of measurement

Based on registration of time and date on medical file

4

Description

Acute Complications

Timepoint

Up to 48 hours

Method of measurement

Physical Examination, inspection and paraclinic data

5

Description

Respiratory rate per minute

Timepoint

hour to hour up to 48 hours

Method of measurement

physical examination and inspection

Secondary outcomes

1

Description

Level of Consciousness

Timepoint

hour to hour Up to 48 hours

Method of measurement

Physical Examination and assessment of neurologic system

2

Description

Need to naloxone
Timepoint
During 48 hrs admission
Method of measurement
Dose of Naloxone Received (mg)

Intervention groups

1

Description

Intervention group; After emergency management (if needed) the patients in intervention group will take a single dose of 50mg naltrexone orally . During the hospital stay, the prevalence of respiratory depression or respiratory arrest, and loss of consciousness will be assess in these patients hourly by physical examination and monitoring of oxygenation and CO2 pressure of the blood (based on arterial blood gases analysis), and the O2 saturation by pulse oxymetry.

Category

Treatment - Drugs

2

Description

Control group; The patients in control group after emergency management (if needed) will take a placebo drug. These patient during hospital admission will monitor regarding to respiratory depression or arrest and loss of consciousness by hourly physical examination, arterial Pco2 and oxygenation by arterial blood gas and pulseoxymetry respectively.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Toxicology emergency ward and poisoning ward of Loghman-Hakim Hospital

Full name of responsible person

Dr Hossein Hasanian-Moghaddam, Dr Abas Aghabiklooei

Street address

Loghman-Hakim Hospital ,Kamali Ave, Makhsus St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Loghman-Hakim Toxicological Reserch Center dependent to Shahid-Beheshti University

Full name of responsible person

Abdolkarim Pajoumand

Street address

Loghman-Hakim Hospital, Kamali Ave., Mahksus Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Loghman-Hakim Toxicological Reserch Center dependent to Shahid-Beheshti University

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hosein Hassanian-Moghaddam

Position

Research and Educational deputy of Clinical Toxicology Department

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Forensic Medicine Especialist, Fellowship in Medical Toxicology

Other areas of specialty/work

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Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein Hassanian-Moghaddam

Position

Assistant Professor of Department of Medical
Toxicology

Other areas of specialty/work**Street 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