

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of 50 - and 100 - mg doses of Naltrexone in controlling apnea and bradypnea in non-addicted patients overdosed with methadone

Protocol summary

Summary

A total of 70 non-addicted patients who have referred with methadone overdose will randomly be assigned into either A or B groups receiving 100 or 50 mg of naltrexone capsules. The patients will firstly be evaluated by narcan challenge test to be sure that they are not addicted. 0.2- mg, 0.6-mg, and 1.2-mg narcan doses are administered. If the patients do not develop signs and symptoms of withdrawal, they are considered to be opioid-naïve and receive the naltrexone capsules. All patients, researchers and data collectors will be blind to the dose of naltrexone administered. They will be followed for 24 hours for possible reversal of signs and symptoms of opioid overdose (apnea/bradypnea/cyanosis/respiratory acidosis). After 24 hours, they will be discharged and followed later by phone calls. The two groups will finally be compared regarding the occurrence of complications and mortality to determine the best dose of naltrexone in prevention of the opioid syndrome reversal.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603083913N2**

Registration date: **2016-05-23, 1395/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-23, 1395/03/03

Registrant information

Name

Shahin Shadnia

Name of organization / entity

Shaheed Beheshti University of Medical Sciences

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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

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of 50 - and 100 - mg doses of Naltrexone in controlling apnea and bradypnea in non-addicted patients overdosed with methadone

Public title

Comparison of 50 - and 100 - mg doses of Naltrexone in controlling apnea and bradypnea in non-addicted patients overdosed with methadone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non-addicted patients to any type of opioid who have referred with methadone overdose; existence of overdose signs and symptoms (bradypnea/apnea/miosis/loss of consciousness) Exclusion criteria: patients over 65 years

and younger than 12 years of age; respiratory complications (ARDS, pulmonary edema, etc) due to narcotic administration; history of cardiovascular diseases; unstable patients in whose treatment should be initiated immediately (need to be immediately intubated; general indications for 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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee; Shahid Beheshti University of Medical Science

Street address

Shahid Beheshti University of Medical Science

City

Tehran

Postal code

NA

Approval date

2016-02-10, 1394/11/21

Ethics committee reference number

IR.SBMU.RAM.REC.1394.531

Health conditions studied

1

Description of health condition studied

Non-addicted patients overdosed with methadone

ICD-10 code

T40.3

ICD-10 code description

Methadone

Primary outcomes

1

Description

reversal of overdose signs and symptoms(bradypnea/apnea)

Timepoint

24-hour monitoring

Method of measurement

clinical evaluation of the patients (regarding vital signs and clinical manifestations)

Secondary outcomes

1

Description

Control of the respiratory acidosis

Timepoint

twice in 24 hours

Method of measurement

interpretation of the patients' ABG

Intervention groups

1

Description

Capsule Naltrexone 100 mg,Oral,single dose

Category

Treatment - Drugs

2

Description

Capsule Naltrexone 50 mg,Oral,single dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Dr Ali Ostadi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Toxicological Research Center

Full name of responsible person

Mrs Morsali
Street address
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
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

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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