

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of naloxone & buprenorphine on reversal of Opioid Overdose Syndrome and withdrawal in Methadone - Dependant Patients; An experimental Study

Protocol summary

Summary

A total of 90 opioid-dependant patients who have referred after methadone overdose will randomly be assigned into either buprenorphine or naloxone group. the patients in buprenorphine group will themselves be assigned into two groups of 5 microgram/kg and 10 microgram/kg. The patients in the naloxone group will receive naloxone with 0.05 mg initial dose and the doubling incremental dosing every 3-5 minutes. The patients will then be watched for signs and symptoms of withdrawal or response to the treatment (reversal of apnea, cyanosis, loss of consciousness, etc). The three groups will finally be compared regarding these variables and outcome. If they are not responding to the treatments given, they will be intubated and excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011020624N1**
Registration date: **2015-11-27, 1394/09/06**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-11-27, 1394/09/06

Registrant information

Name

Nasim Zamani

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-03-21, 1395/01/02

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of naloxone & buprenorphine on reversal of Opioid Overdose Syndrome and withdrawal in Methadone - Dependant Patients; An experimental Study

Public title

Comparison of naloxone & buprenorphine on reversal of Opioid Overdose Syndrome and withdrawal in Methadone - Dependant Patients; An experimental Study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all opioid-dependant patients who refer after methadone overdose will be included and randomly assigned into either case (buprenorphine with two different doses) or control (naloxone) group. Exclusion criteria: 1-Those younger than 12 years of age and older than 100 years will be excluded. 2- Patients with multiple drug overdoses will be excluded. 3-Patients who do not

respond to the buprenorphien and naloxone doses and are in life-threatening situation will be intubated and excluded from the study.

Age

From **12 years** old to **100 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University Medical Sciences Ethics Committee

Street address

Shahid Beheshti University of Medical Sciences,
Yaman St, Velenjak

City

Tehran

Postal code

Approval date

2015-07-26, 1394/05/04

Ethics committee reference number

IR.SBMU.RAM.REC.1394.62

Health conditions studied

1

Description of health condition studied

Methadone Overdose

ICD-10 code

T40.3

ICD-10 code description

Poisoning by Methadone

Primary outcomes

1

Description

Reversal of Respiratory Depression

Timepoint

1 min

Method of measurement

reversal of respiratory rate

Secondary outcomes

1

Description

Reversal of cyanosis and increased O2 Saturation

Timepoint

2 minutes

Method of measurement

Pulse Oximetry

Intervention groups

1

Description

Narcan Injection (case group)

Category

Treatment - Drugs

2

Description

Buprenorphine (5micro/kg; 1st Control Group)

Category

Treatment - Drugs

3

Description

Buprenorphine (10micro/kg; 2nd Control group)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Clinical Toxicology-Loghman Hakim Hospital

Full name of responsible person

Dr Nasim Zamani

Street address

South Karegar Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mopstafa Rezaei Tavirani

Street address

Shahid Beheshti University of Medical Sciences,
Yaman Street, Velenjak

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Grant name

Grant code / Reference number

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

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

Dr. Nasim Zamani

Position

Assistant Professor-

Other areas of specialty/work

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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