Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 been assigned into either buprenorphine or naloxone group. the patients in buprenorphine group will themselves been assined 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 consiousness, 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)
Phone
+98 21 5542 4041
Email address
nasim.zamani@sbmu.ac.ir

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-treathening 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 Commitee

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
City
Tehran
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
Street address
Department of Clinical Toxicology-Loghman Hakim Hospital
City
Tehran
Postal code
Phone
+98 21 5542 4041
Fax
Email
nasim.zamani@gmail.com
Web page address

Person responsible for scientific 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
Street address
Department of Clinical Toxicology-Loghman Hakim Hospital
City
Tehran
Postal code
Phone
+98 21 5542 4041
Fax
Email
nasim.zamani@gmail.com
Web page address

Person responsible for updating data

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
Street address
Department of Clinical Toxicology-Loghman Hakim Hospital
City
Tehran
Postal code
Phone
+98 21 5542 4041
Fax
Email
nasim.zamani@gmail.com
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