Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of naloxone and naltrexone in the treatment of methadone poisoning in patients referred to the emergency department

Protocol summary

Summary

This clinical trial, randomized, double-blind study, was done on 80 non-addicted patient with intoxication with methadone. Inclusion criteria: age 20 to 60 years, obtaining informed consent from a parent or guardian patients into the study. Exclusion criteria: drug, pregnancy and breastfeeding, history of uncontrolled systemic underlying disease, especially liver disease (liver failure, hepatitis, etc.), cardiovascular disease and heart rhythm, especially supraventricular dysrhythmias ; at the same time multiple trauma, especially trauma to the head and the possibility of increased ICP; a history of seizures; a history of hypersensitivity to naloxone or naltrexone consumption in the past; recent use of narcotic analgesics, complications during the administration of a drug abuser.Patients administered an initial dose of 4.0 to 2 mg amount of naloxone (1 to 5 injections of 4.0 mg naloxone) and diluted intravenous or without dilution (in case of loss of consciousness, a history of addiction) and are when the patients returned to consciousness, the initial dose is repeated every 2 to 3 minutes. After awareness of patients and monitor acute toxicity, patients random 1: 1 into two groups of 40 (group 1: receiving naloxone for conservative treatment, group 2 received naltrexone for the treatment of preservatives) are included. Group 1, 3/2 dose that the patient's consciousness was caused in the first hour, 3/2 × 3/2 initial dose in the second hour, 3/2 × 3/2 × 3/2 initial dose in the third hour and 3 / 2 × 3/2 × 3/2 × 3/2 initial dose of the fourth hour, every hour infusions received. Group 2, equivalent dose of naloxone that consciousness is, in the form of Naltrexone receiving oral form. Vital signs and other clinical parameters in hours, 1, 2, 3, 4 and 12 after recovery consciousness, were recorded. Data were analyzed using SPSS 18 statistical software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100623552N11**
Registration date: **2016-10-18, 1395/07/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-18, 1395/07/27

Registrant information

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Abolfazl Jokar
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-12-02, 1393/09/11

Expected recruitment end date

2016-01-10, 1394/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of naloxone and naltrexone in the treatment of methadone poisoning in patients referred to the emergency department

Public title
Comparison of naloxone and naltrexone in the treatment of methadone poisoning in patients referred to the emergency department
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age 20 to 60 years, obtaining informed consent from a parent or guardian patients into the study. Exclusion criteria: drug, pregnancy and breastfeeding, history of uncontrolled systemic underlying disease, especially liver disease (liver failure, hepatitis, etc.), cardiovascular disease and heart rhythm, especially supraventricular dysrhythmias ; at the same time multiple trauma, especially trauma to the head and the possibility of increased ICP; a history of seizures; a history of hypersensitivity to naloxone or naltrexone consumption in the past; recent use of narcotic analgesics, complications during the administration of a drug abuser
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single 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 of Arak University of Medical Sciences
Street address
Alamolhoda, Maskan, Arak
City
Arak
Postal code
Approval date
2014-09-23, 1393/07/01
Ethics committee reference number
93-169-17

Health conditions studied

1

Description of health condition studied
Poisoning by methadone
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Level of consciousness
Timepoint
1, 2, 3, 4 and 12 hours after intervention
Method of measurement
Increasing the level of consciousness

2

Description
Respiratory function
Timepoint
1, 2, 3, 4 and 12 hours after intervention
Method of measurement
Improve respiratory function

Secondary outcomes

1

Description
The number of heart beats per minute
Timepoint
1, 2, 3, 4 and 12 hours after intervention
Method of measurement
Measurable clinical responses

2

Description
Respiratory rate
Timepoint
1, 2, 3, 4 and 12 hours after intervention
Method of measurement
Measurable clinical responses

3

Description
Body temperature (° C)
Timepoint
1, 2, 3, 4 and 12 hours after intervention

Method of measurement
Measurable clinical responses

4

Description
Systolic and diastolic blood pressure
Timepoint
1, 2, 3, 4 and 12 hours after intervention
Method of measurement
Measurable clinical responses

Intervention groups

1

Description
Group 1: 3.2, which causes the patient's consciousness was embroidered in the first hour, 3/2 × 3/2 initial dose in the second hour, 3/2 × 3/2 × 3/2 initial dose in the third hour and 3 / 2 × 3/2 × 3/2 × 3/2 initial dose of the fourth hour, every hour infusions received.
Category
Treatment - Drugs

2

Description
Group 2: equivalent dose of naloxone that consciousness is, in the form of Naltrexone receiving oral form.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak University of Medical sceinces
Full name of responsible person
dr.Jokar Abolfazl
Street address
Valiasr Hospital Arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Arak University of Medical Sciences
Full name of responsible person
Dr. Rafiee Mohammad
Street address
Arak, School of Medicine
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Arak 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
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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