

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Abolfazl Jokar

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 2134

Email address

dr.a.jokar@gmail.com

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, $3/2 \times 3/2$ initial dose in the second hour, $3/2 \times 3/2 \times 3/2$ initial dose in the third hour and $3/2 \times 3/2 \times 3/2 \times 3/2$ 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 sciences

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

Arak University of Medical sciences

Full name of responsible person

Dr. Abolfazl Jokar

Position

Emergency medicine specialist

Other areas of specialty/work

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Contact

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Full name of responsible person

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Position

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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