

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Impact of Ondansetron on withdrawal syndrome and fentanyl requirement in opium addicted patients under general anesthesia.

Protocol summary

Summary

With the spread of narcotics in human societies, it is important to consider the symptoms and conditions of addicted people and to treat these symptoms in health centers. The purpose of this study was to evaluate the effect of ondansetron on the symptoms of drug metabolism syndrome and the need for fentanyl in generalized addicts in a double-blinded study. Entry requirements include the age of the patient aged between 19-70 years and addicted to opium compounds and the exclusion criteria including the use of several opiate drugs simultaneously or prolonged the patient's operation or the seizure and maintenance of the patient with medication other than the protocol (fentanyl) to be selected. Patients in the department who have chosen the conditions for entering the study and after giving a complete and accurate description to the patient and taking pictures in a group, and to each group of these patients, different doses of andestron include Group A: mg 4 and Group B: 8 mg and Group C: Placebo containing 2 ml of distilled water, injected intravenously 15 minutes prior to anesthesia. After the patient enters the operating room, the registered form for the signs of withdrawal is checked, and before the anesthesia process, vital signs and biochemical parameters are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051333940N1**

Registration date: **2017-07-17, 1396/04/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-17, 1396/04/26

Registrant information

Name

Hamid Reza Rahimi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5437

Email address

h_rahimi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Pharmaceutical Research Center, Kerman University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of Ondansetron on withdrawal syndrome and fentanyl requirement in opium addicted patients under general anesthesia.

Public title

Impact of Ondansetron on withdrawal syndrome and fentanyl requirement in opium addicted patients under general anesthesia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients addicted to opiates in the age range of 19-70 years and have fractures. Exclusion criteria: addicted patients who have multi-drug use together or surgery prolongation or induction and maintenance of anesthesia with other Protocol that fentanyl not included.

Age

From **19 years** old to **70 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Pharmaceutical Research Center of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Haft Bagh Blvd.

City

Kerman

Postal code

7616911319

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

IR.KMU.REC.1395.977

Health conditions studied

1

Description of health condition studied

Addicted patients with opioid dependence

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

Withdrawal signs and pain

Timepoint

Up to 2h after ondansetron injection

Method of measurement

Observation

2

Description

Withdrawal signs and pain

Timepoint

Visual analogue scale

Method of measurement

Up to 2h after injection of ondansetron

Secondary outcomes

1

Description

Pain

Timepoint

Up to 2h after ondansetron injection

Method of measurement

Observation

Intervention groups

1

Description

Biography of included patients is registered and distributed in one of the study groups, and to each group of these patients, different doses of 4 mg and 8 mg of andestron are injected intravenously 15 minutes before anesthesia.

Category

Treatment - Drugs

2

Description

The control group received all the conditions for the treatment group with ondansetrone, except that they received a placebo containing 2 ml of distilled water, which is injected intravenously 15 minutes before anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar-Kerman hospital

Full name of responsible person

Morteza Hashemian

Street address

Gharani Ave.

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmaceutical Research Center, Faculty of Pharmacy

Full name of responsible person

Gholamreza Dehghan-Nodeh

Street address

Kerman University of Medical Sciences, 7 Bagh Blv.

City

Kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pharmaceutical Research Center, Faculty of Pharmacy

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

Kerman Faculty of Pharmacy

Full name of responsible person

Hamid Reza Rahimi

Position

Assistant Prof.

Other areas of specialty/work

Street address

Block L, Faculty of Pharmacy, 7 Bagh Blvd.

City

Kerman

Postal code

7616911319

Phone

+98 34 3132 5437

Fax

+98 34 3132 5003

Email

h_rahimi@kmu.ac.irhamidrtr@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Toxicology and Pharmacology, Faculty of Pharmacy

Full name of responsible person

Hamid Reza Rahimi

Position

Assistant Prof.

Other areas of specialty/work

Street address

Block L, Faculty of Pharmacy, 7 Bagh Blvd.

City

Kerman

Postal code

7616911319

Phone

+98 34 3132 5437

Fax

+98 34 3132 5003

Email

h_rahimi@kmu.ac.irhamidrtr@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Toxicology and Pharmacology, Faculty of Pharmacy

Full name of responsible person

Hamid Reza Rahimi

Position

PhD

Other areas of specialty/work

Street address

Block L, Faculty of Pharmacy, 7 Bagh Blvd.

City

Kerman

Postal code

7616911319

Phone

+98 34 3132 5437

Fax

+98 34 3132 5003

Email

h_rahimi@kmu.ac.irhamidrtr@yahoo.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