

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison between methadone and opium effectiveness in control of agitation due to withdrawal syndrome in opium addicted patients admitted to the ICU of Kerman Shaheed Bahonar hospital

Protocol summary

Summary

Opium is the main abusing compound in Iran. In ICU opium addicted patients withdrawal syndrome will cause agitation and altering patient's responsiveness. Thus we have to replace opium in these patients. The aim of this study is to evaluate opium tincture with methadone syrup as the standard replacement therapy. Based on DSM-4 criteria, 2 groups of opium addicted patients were randomly included to the study. If renal or hepatic failure occur, patients will be excluded from the study. Age of patients population is between 18 to 60 yrs. Group 1 receive opium tincture and the other take methadone syrup as much as to put them in score 0 of Richmond agitation-sedation scale. And to control patients agitation; moreover, vital signs would be evaluated before, during and after the ending study. Finally we evaluate that which of these medicines can control patient's agitation and vital signs with minimum of dose and side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107011836N2**

Registration date: **2011-09-15, 1390/06/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-09-15, 1390/06/24

Registrant information

Name

Seyed Mojtaba Sohrevardi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1320 5001

Email address

smsohrevardi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2011-08-06, 1390/05/15

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between methadone and opium effectiveness in control of agitation due to withdrawal syndrome in opium addicted patients admitted to the ICU of Kerman Shaheed Bahonar hospital

Public title

Comparison between methadone and opium effectiveness in control of agitation due to withdrawal syndrome in opium addicted patients admitted to the ICU of Kerman Shaheed Bahonar Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Patients who addicted to opium and admitted to the ICU and they can tolerate methadon syrup or opium tincture

by oral or gavage include to the study. If acute renal failure or hepatic failure happen to patients they will be excluded from the study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

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 Kerman university of medical sciences

Street address

Research advisory of KMU, Blvd jomhuri eslami

City

Kerman

Postal code

Approval date

2011-08-05, 1390/05/14

Ethics committee reference number

k/90/145

Health conditions studied

1

Description of health condition studied

opium addiction

ICD-10 code

F11.2

ICD-10 code description

Mental and behavioural disorders

Primary outcomes

1

Description

Richmond agitation-sedation score

Timepoint

BID

Method of measurement

standard richmond sheet

Secondary outcomes

1

Description

Respiratory rate

Timepoint

Multiple

Method of measurement

Ventilator

2

Description

Blood pressure

Timepoint

Every 3 hr

Method of measurement

Sphygmomanometer

3

Description

Heart rate

Timepoint

Multiple

Method of measurement

Cardiovascular monitoring system

Intervention groups

1

Description

Intervention group take opium tincture to prevent withdrawal syndrome and reach Richmond scale to score 0

Category

Treatment - Drugs

2

Description

Control group take methadon syrup for prevention of withdrawal syndrome and getting score 0 of Richmond scale

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kerman Shahid Bahonar Hospital
Full name of responsible person
Street address
City
kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr Reza Malekpour Afshar
Street address
Vice chancellor for research
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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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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