

# 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**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Seyed Mojtaba Sohrevardi  
**Position**  
Faculty member- clinical pharmacist  
**Other areas of specialty/work**  
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**Phone**  
+98 913 451 2422  
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smsohrevardi@yahoo.com

#### Web page address

#### Person responsible for scientific inquiries

#### Contact

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#### Person responsible for updating data

#### Contact

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Pharm D., Ph.D- Clinal Pharmacist  
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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*