

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effect of different doses of Buprenorphine (32 mg- 64 mg- 96 mg) on the reduction of opioid withdrawal symptoms and reduction of their depression and suicidal thoughts

#### Protocol summary

##### Summary

In this double blind trial 60 hospitalized opioid dependent men are randomly divided into three groups (each group has 20 patients) and give 32 mg buprenorphine to first group, 64 mg buprenorphine to second group and 96 mg buprenorphine to third group as a single dose only. The patients will be followed up for two weeks and evaluate the withdrawal symptoms, depression and suicidal thoughts by interview and also beck depression and suicidal thoughts questionnaires. The goal of this study is to find the best treatment dose of buprenorphine for reduction of withdrawal symptoms, depression and suicidal thoughts in opiod dependents and find the best choice.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016071325160N4**

Registration date: **2017-01-24, 1395/11/05**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-24, 1395/11/05

##### Registrant information

###### Name

Jamshid Ahmadi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3627 3070

##### Email address

ahmadij@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2016-06-21, 1395/04/01

##### Expected recruitment end date

2018-02-22, 1396/12/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of different doses of Buprenorphine (32 mg- 64 mg- 96 mg) on the reduction of opioid withdrawal symptoms and reduction of their depression and suicidal thoughts

##### Public title

Effect of Buprenorphine on reduction of withdrawal symptoms, depression and suicidal thoughts

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria:age between 16 to 60 y/o; informed consent;Opioid dependence Exclusion criteria:Patients unwilling to participate at beginning or during the study; use of other substances except Opioid as of the main substance.

##### Age

From **16 years** old to **60 years** old

##### Gender

Male

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences

##### Street address

ice Chancellery for Research Affairs, Shiraz University of Medical Sciences, Zand Blvd

##### City

Shiraz

##### Postal code

7194634786

#### Approval date

2016-08-21, 1395/05/31

#### Ethics committee reference number

IR.SUMS.REC.1395.102

## Health conditions studied

### 1

#### Description of health condition studied

Opioid dependency

#### ICD-10 code

F11

#### ICD-10 code description

Mental and behavioural disorders due to use of opioids

## Primary outcomes

### 1

#### Description

reduction of depression in opioid dependents and find the best choice

#### Timepoint

before the first dose and first day to 14 days

#### Method of measurement

interview and questionnaires

### 2

#### Description

reduction of withdrawal symptoms in opioid dependents and find the best choice

#### Timepoint

before the first dose and first day to 14 days

#### Method of measurement

interview and questionnaire

### 3

#### Description

reduction of suicidal thoughts in opioid dependents and find the best choice

#### Timepoint

before the first dose and first day to 14 days

#### Method of measurement

interview and questionnaires

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

32 mg buprenorphine is given as a single dose to patients and evaluated withdrawal symptoms, depression and suicidal thoughts for two weeks.

#### Category

Treatment - Drugs

### 2

#### Description

64 mg buprenorphine is given as a single dose to patients and evaluated withdrawal symptoms, depression and suicidal thoughts for two weeks.

#### Category

Treatment - Drugs

### 3

#### Description

96 mg buprenorphine is given as a single dose to patients and evaluated withdrawal symptoms, depression and suicidal thoughts for two weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ebne Sina Hospital

##### Full name of responsible person

Jamshid Ahmadi M.D

**Street address**

Ebne Sina Hospital, Hafeziye street

**City**

Shiraz

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Basir Hashemi

**Street address**

ice Chancellery for Research Affairs, Shiraz University of Medical Sciences, Zand Blvd

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

**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*

### 2

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyyed Basir Hashemi

**Street address**

ice Chancellery for Research Affairs, Shiraz University of Medical Sciences, Zand Blvd

**City**

shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Jamshid Ahmadi M.D.

**Position**

Proffesor

**Other areas of specialty/work**

**Street address**

Third floor, Neshat Complex, Daneshjoo Street

**City**

Shiraz

**Postal code**

**Phone**

+98 71 3646 1511

**Fax**

**Email**

jamshid\_ahmadi@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Jamshid Ahmadi

**Position**

Professor

**Other areas of specialty/work**

**Street address**

Third floor, Neshat Complex, Daneshjoo Street

**City**

Shiraz

**Postal code**

7194654743

**Phone**

+98 71 3646 1511

**Fax**

**Email**

jamshid\_ahmadi@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Jamshid Ahmadi

**Position**

Professor of Psychiatry, Director of Substance Abuse and Mental Health Research Center

**Other areas of specialty/work****Street address**

Third floor, Neshat Complex, Daneshjoo Street

**City**

Shiraz

**Postal code**

7194654743

**Phone**

00

**Fax****Email**

jamshid\_ahmadi@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*