

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Assessment of effect of different doses of buprenorphine (16,32 mg) on reduction of anxiety level and craving in opioid dependents

#### Protocol summary

##### Summary

In this double blind (both patients, and researchers are blind to the medications) randomized (the patients are randomly located in one of the three arms. We use a standard randomization procedure), placebo controlled trial at least 60 hospitalized opioid dependent men are divided randomly into three groups (each group has at least 20 patients) and give 32 mg buprenorphine to first group, 16 mg buprenorphine to second group and placebo to third group as a single dose only. The patients will be followed up for at least 4 days and assess the anxiety, depression, suicidal thoughts and withdrawal symptoms by interview and also Hamilton anxiety, beck depression and suicidal thoughts questionnaires. The objective of this trials to find the best treatment dose of buprenorphine for reduction of withdrawal symptoms ,anxiety, depression and suicidal thoughts in opioid dependents and find the best choice.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017082225160N11**

Registration date: **2017-09-10, 1396/06/19**

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

Last update:

Update count: **0**

##### Registration date

2017-09-10, 1396/06/19

##### 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

2017-07-23, 1396/05/01

###### Expected recruitment end date

2018-03-20, 1396/12/29

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Assessment of effect of different doses of buprenorphine (16,32 mg) on reduction of anxiety level and craving in opioid dependents

###### Public title

Assessment of effect of different doses of buprenorphine (16,32 mg) on reduction of anxiety level and craving in opioid dependents

###### 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

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)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Both patients, and researchers are blind to the medications. Randomization: in a double blind manner the patients are randomly located in one of the three arms. We use a standard randomization procedure generated by computer to have random sample set.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences.

##### Street address

Shiraz University of Medical Sciences, Zand blvd

##### City

Shiraz

##### Postal code

#### Approval date

2017-06-14, 1396/03/24

#### Ethics committee reference number

IR.SUMS.MED.REC.1396.65

## Health conditions studied

### 1

#### Description of health condition studied

Opioid dependency

#### ICD-10 code

F11

#### ICD-10 code description

Mental and behavioral disorders due to use of opioids

## Primary outcomes

### 1

#### Description

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

#### Timepoint

before the first dose and first day to 4 days

#### Method of measurement

by interview based on DSM-5 and questionnaire (Craving and withdrawal questionnaire)

## Secondary outcomes

### 1

#### Description

Change of anxiety, depression in opioid dependents and find the best choice, suicidal thoughts

#### Timepoint

before the first dose and first day to 4 days

#### Method of measurement

by interview based on DSM-5 criteria and questionnaires (Ham-A, BSSI, BDI)

## Intervention groups

### 1

#### Description

32 mg buprenorphine is given as a single dose to patients and evaluate anxiety, depression, suicidal thoughts and withdrawal symptom for at least 4 days.

#### Category

Treatment - Drugs

### 2

#### Description

16 mg buprenorphine is given as a single dose to patients and evaluate anxiety, depression, suicidal thoughts and withdrawal symptom for at least 4 days.

#### Category

Treatment - Drugs

### 3

#### Description

Placebo is given as a single dose to patients and evaluate anxiety, depression, suicidal thoughts and withdrawal symptom for at least 4 days.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

EbneSina Hospital

##### Full name of responsible person

Jamshid Ahmadi M.D

**Street address**

EbneSina Hospital, Hafeziye street

**City**

Shiraz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor of Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Basir Hashemi

**Street address**

vice 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**

Vice chancellor of Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Jamshid Ahmadi M.D.

**Position**

Professor

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

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**Fax****Email****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*