

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

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Email address

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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

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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**

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Full name of responsible person

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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