

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of different doses of Buprenorphine on reduction of withdrawal symptoms, anxiety, depression and suicidal thoughts

Protocol summary

Summary

In this placebo controlled, double blind trial at least 60 hospitalized opioid dependent men are randomly divided into three groups (each group has 20 patients) and give 8 mg buprenorphine to first group, 2 mg buprenorphine to second group and 96 placebo to third group as a single dose only. The patients will be followed up for at least 5 days and evaluate the withdrawal symptoms, anxiety, depression and suicidal thoughts by interview and also Hamilton anxiety, 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 ,anxiety, depression and suicidal thoughts in opiod dependents and find the best choice.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071925160N6**

Registration date: **2017-08-04, 1396/05/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-04, 1396/05/13

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

Vice chancellor for research Shiraz University of Medical Sciences

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2018-04-30, 1397/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of different doses of Buprenorphine on reduction of withdrawal symptoms, anxiety, depression and suicidal thoughts

Public title

Efficacy of different doses of Buprenorphine on reduction of withdrawal symptoms, anxiety, 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

4

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand blvd

City

Shiraz

Postal code

Approval date

2010-08-01, 1389/05/10

Ethics committee reference number

IR.SUMS.REC.1396.84

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

Withdrawal symptoms in opioid dependents

Timepoint

before the first dose and first day to 4 days

Method of measurement

Interview and questionnaire

Secondary outcomes

1

Description

anxiety, depression in opioid dependents

Timepoint

Before the first dose and first day to 4 days

Method of measurement

Interview and questionnaires

Intervention groups

1

Description

Intervention group 1: 8 mg buprenorphine is given as a sublingual single dose to patients and evaluated for at least 5 days.

Category

Treatment - Drugs

2

Description

Intervention group 2: 2 mg buprenorphine is given as a sublingual single dose to patients and evaluated for at least 5 days.

Category

Treatment - Drugs

3

Description

Control group: Placebo is given as a sublingual single dose to patients and evaluated for at least 5 days.

Category

Treatment - Drugs

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

Shiraz University of Medical Sciences

Full name of responsible person

SeyedBasirHashemi

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

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**

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 M.D.

Position

Professor

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

Third floor, Neshat Complex, Daneshjoo Street

City

Shiraz

Postal code**Phone**

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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