Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 opiod 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 opiod 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 thouhgts in opiod 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