Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 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
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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
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EbneSina Hospital, Hafeziye street
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Sponsors / Funding sources

1

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Full name of responsible person
SeyedBasirHashemi

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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
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

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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