

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Compering the effect of different doses of buprenorphine on methamphetamine dependency treatment

Protocol summary

Study aim

Determination and comparison of the effects of different doses of buprenorphine on treatment of methamphetamine users in patients admitted

Design

The goal of study is to compare the effect of deiffrent dosses of Buprenorphine on methamphetamine dependency treatment. in this single trial at least 60 patient will be selected and by simple random sampling (sortiton) will be divided to 3 group and each group include 20 patients. each group recives one dose of Buprenorphine from deiffrent dooses (0.1,1,8)mg QD

Settings and conduct

The questionnaire is asked daily for 4 days in ebne sina hospital

Participants/Inclusion and exclusion criteria

Induction criteria: 1)Age 18-50 2)Inform consent 3)Methamphetamine depanded; Exclusion criteria: 1)Patient unwilling to participle at beginning or during the study 2)Use of another substance except Methamphetamine as of the main substance

Intervention groups

The questionnaire asked daily and it shows the effect of drug and this medicine isn't have side effect

Main outcome variables

Carving

General information

Reason for update

Acronym

N/A

IRCT registration information

IRCT registration number: **IRCT20170715035094N4**

Registration date: **2019-03-07, 1397/12/16**

Registration timing: **retrospective**

Last update: **2019-03-07, 1397/12/16**

Update count: **0**

Registration date

2019-03-07, 1397/12/16

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 3070

Email address

bazrafshan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Equipment and items to be purchased: 200 buprenorphine ,each one is 10,000 Rials, totally 2,000,000 Rials ,Travel costs: Taxi vehicle, each time is 50,000 Rials , two person, totally 6,000,000 Rials ,copy writing costs: 2,000,000 Rials

Expected recruitment start date

2017-11-03, 1396/08/12

Expected recruitment end date

2018-10-04, 1397/07/12

Actual recruitment start date

2018-01-24, 1396/11/04

Actual recruitment end date

2018-11-11, 1397/08/20

Trial completion date

2019-03-12, 1397/12/21

Scientific title

Compering the effect of different doses of buprenorphine on methamphetamine dependency treatment

Public title

The effect of buprenorphine on methamphetamine dependency treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1)Age 18-50 2) inform consent 3)methamphetamine depanced

Exclusion criteria:

1)patient unwilling to participle at beginning or during the study, 2)use of another substance except Methamphetamine as of the main substance

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this double-blind study 60 patients are selected and with using the computer generated random sampling program, these 60 people are divided into 3 groups of 20 people.This computer program will automatically divide these 60 people into three groups of 20 people completely randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Researchist; Emulator Analyzer; Participant don't know about doses of drugs and groups during test

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Science

Street address

Shiraz University of Medical Science , Znad Blvd

City

Shiraz

Province

Fars

Postal code

7194634786

Approval date

2017-10-16, 1396/07/24

Ethics committee reference number

IR.SUMS.MED.REC.1396.64

Health conditions studied

1

Description of health condition studied

Methamphetamine Dependency

ICD-10 code

F19

ICD-10 code description

Other psychoactive substance related disorders

Primary outcomes

1

Description

Craving

Timepoint

Before starting the intervention and daily for 4 days after starting the drug

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Depression

Timepoint

Before starting the intervention and daily for 4 days after starting the drug

Method of measurement

Questionnaire

2

Description

Suicide

Timepoint

Before starting the intervention and daily for 4 days after starting the drug

Method of measurement

Questionnaire

3

Description

Anxiety

Timepoint

Before starting the intervention and daily for 4 days after starting the drug

Method of measurement

Questionnaire

4

Description

Withdrawal

Timepoint

Before starting the intervention and daily for 4 days after starting the drug

Method of measurement

Questionnaire

Intervention groups

1

Description

We will use Buprenorphine 0.1 mg po QD for one group at least 14 days

Category

Treatment - Drugs

2

Description

We will use Buprenorphine 8 mg po QD for one group at least 14 days

Category

Treatment - Drugs

3

Description

We will use Buprenorphine 1 mg po QD for one group at least 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebne Sina Hospital

Full name of responsible person

Amir Bazrafshan M.d

Street address

Ebne Sina Hospital, Hafeziye street

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3228 0236

Email

sinahosp@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Province

Fars

Postal code

71348-14336

Phone

+98 71 3481 4336

Email

info@sums.ac.ir

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Amir Bazrafshan M.D

Position

M.D

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Hafez Hospital, Abiverdi street

City

Shiraz

Province

Fars

Postal code

719434786

Phone

+98 71 3627 9319

Fax

Email
bazrafshan_amir@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
Amir Bazrafshan M.D
Position
M.D
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Hafez Hospital, Abiverdi street
City
Shiraz
Province
Fars
Postal code
7194534786
Phone
+98 71 3627 9319
Fax
Email
bazrafsham_amir@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
Amir Bazrafshan M.D
Position

M.D
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Hafez Hospital, Abiverdi street
City
Shiraz
Province
Fars
Postal code
7194634786
Phone
+98 71 3627 9319
Fax
Email
bazrafshan_amir@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available