

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigation on efficacy of Buprenorphine Maintenance Treatment (BMT) for Methamphetamine dependants; a before - after phase II clinical trial

Protocol summary

Summary

Methamphetamine dependency is one of the serious social concerns in Iran and unfortunately there are no drug of choice for this dependency. The aim of this study is Investigation on efficacy of buprenorphine maintenance treatment (BMT) for methamphetamine dependants as a before - after phase II clinical trial on 21 patients in Qazvin. Inclusion criteria are ability to reading and writing and age between 18 and 55. Exclusion criteria are all of contraindications of buprenorphine and no agreement to participation in study. Firstly, participants will be monitored in one week running period for medical and psychiatric assessments and if they need antipsychotic medications, olanzapine with the minimum dose of 5 mg and maximum dose of 15 mg will be prescribed and also they will fill Leeds dependency questionnaire (LDQ), Obsessive Compulsive Drug Use Scale (OCDUS) questionnaire, lite version of Addiction Severity Index (ASI - Lite) questionnaire, WHO Quality of Life-BREF (WHOQOL-BREF) questionnaire and also Cognitive Abilities Questionnaire (CAQ). In this period, blood sample will be given for LFT study. After running period, participants will be entered in intervention period and they will be visited three times a week and urine rapid tests for methamphetamine, morphine and benzodiazepines will be checked. In addition to receiving buprenorphine in every visits, psychotherapy sessions will be held weekly. LDQ, OCDUS, WHOQOL-BREF and (CAQ) will be filled in 4th, 8th and 12th week again and ASI - Lite questionnaire will be held on 12th week again. After 12 weeks, all participants will be followed for 12 weeks as a follow up period. CAQ will be filled at the end of 24th weeks at the end of follow up period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112315499N1**

Registration date: **2014-07-16, 1393/04/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-16, 1393/04/25

Registrant information

Name

Schwann Shariatirad

Name of organization / entity

Student Research Center of International Campus,
Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5574 5975

Email address

shariatirad@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on efficacy of Buprenorphine Maintenance Treatment (BMT) for Methamphetamine dependants; a before - after phase II clinical trial

Public title

Efficacy of Buprenorphine in the Methamphetamine Dependency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Ability to reading and writing in Persian; 2. Age between 18 and 55 years old; 3. All participants with diagnosis of methamphetamine dependency according to the DSM IV criteria; 4. Agreement to participating in study; Exclusion criteria: 1. Participants currently enrolled in another investigational device or drug trial or previously enrolled (within last 30 days) in investigative research of a device or pharmaceutical agent; 2. Co - use of methamphetamine and methadone; 3. Inability to tolerate buprenorphine; 4. Presence of any liver failure such as hepatitis; 5. History of any lung disease; 6. Presence of any thyroid disease such hypothyroidism or hyperthyroidism; 7. Presence of adrenal gland disease such as addison disease; 8. Presence of kidney failure such as CRF, ARF, etc. 9. Presence of heart failure; 10. Presence of prostatic hyperplasia or urethra tightness; 11. History of epilepsy or uncontrolled seizures; 12. Presence of any cancer; 13. Pregnancy; 14. Any evidences to confirm participants sail buprenorphine outside the addiction treatment center or any evidences to confirm participants will not use buprenorphine; 15. No acceptance to enroll in or continue the study;

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical

Sciences

Street address

6th floor, central building of university, Qods st, Keshavarz blv

City

Tehran

Postal code**Approval date**

2014-05-25, 1393/03/04

Ethics committee reference number

130/322/93/ص

Health conditions studied**1****Description of health condition studied**

Methamphetamine dependency

ICD-10 code

F15

ICD-10 code description

Mental and behavioural disorders due to use of other stimulants, including caffeine

Primary outcomes**1****Description**

existence of methamphetamine in urine samples

Timepoint

three times in a week in first three months, one time a week in second three months of following

Method of measurement

Urine rapid test kit (Methamphetamine)

Secondary outcomes**1****Description**

Obsessive Compulsive Drug Use Scale (OCDUS) score

Timepoint

At the baseline and after that at 4th, 8th and 12th weeks after starting the intervention

Method of measurement

OCDUS questionnaire

2**Description**

remaining until end of study

Timepoint

after the end of the study

Method of measurement

observation of attending patient at the end of study

3**Description**

Score on the Addiction Severity Index (ASI-Lite)

Timepoint

At the baseline and after the end of the 12th week

Method of measurement

ASI-Lite questionnaire

4

Description

Score on the Leeds Dependence Questionnaire (LDQ)

Timepoint

At the baseline and after that at 4th, 8th and 12th weeks after starting the intervention

Method of measurement

LDQ questionnaire

5

Description

Score on the WHO quality of life questionnaire (WHOQOL-BREF)

Timepoint

At the baseline and after that at 4th, 8th and 12th weeks after starting the intervention

Method of measurement

WHOQOL-BREF questionnaire

6

Description

Added at 2015-04-03: Cognitive abilities

Timepoint

Added at 2015-04-03: At the baseline and after that at 4th, 8th, 12th and 24th weeks after starting the intervention

Method of measurement

Added at 2015-04-03: Cognitive Abilities Questionnaire

Intervention groups

1

Description

Buprenorphine 2 mg sublingual as a one tablet daily will be used in this study. This study have not control group and the dosage of the buprenorphine will be assessed in which dosage could control the methamphetamine craving.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayeh Addiction Treatment Center

Full name of responsible person

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

Street address

6th floor, Central building of university, Qods St., Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Faranshimi Company

Full name of responsible person

Dr. Mohammadreza Tehrani-Moghadam

Street address

No 19, Parvin St, Valiasr St

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Faranshimi Company

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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Effatpanah

Position

Assistant professor, Department of psychiatry

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

Taleghani St., Qods St., Enqelab Sq.

City

Tehran

Postal code**Phone**

+98 21 5574 5975

Fax**Email**

m.effatpanah@gmail.com; m-effatpanah@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Student Research Center of International Campus,
Tehran University of Medical Sciences

Full name of responsible person

Schwann Shariatirad

Position

M.D.

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

3rd floor, Education Building, Ziaeian Hospital, Abozar
Sq, Abozar St

City

Tehran

Postal code**Phone**

+98 21 5574 5975

Fax**Email**

shariatirad@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Student Research Center of International Campus,
Tehran University of Medical Sciences

Full name of responsible person

Schwann Shariatirad

Position

Lecturer

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

3rd floor, Education Building, Ziaeian Hospital, Abozar
Sq., Abozar St.

City

Tehran

Postal code**Phone**

+98 21 5574 5975

Fax**Email**

shariatirad@gmail.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