Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 dependents 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