

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of slow-release Methylphenidate on methamphetamine dependence: a double blind and placebo controlled trial

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to evaluate the efficacy of sustained-released methylphenidate in the treatment of methamphetamine dependence. 70 individuals who meet DSM-IV-TR criteria for methamphetamine dependence participate in this 12 weeks trial. The participants randomly will be allocated to two groups. Group 1(N=35) will receive 18 mg/day sustained-released methylphenidate during the first week and 36 mg/day during the second week and then will receive 54 mg/day sustained-released methylphenidate. Group 2(N=35) will receive placebo for 12 weeks. Severity of addiction will be assessed by Addiction Severity Index(ASI) at the beginning and at the end of the study. Craving will be evaluated by a visual analogue craving scale every week . Urinary screening test for methamphetamine will be carried out each weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202281556N38**

Registration date: **2012-03-10, 1390/12/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-03-10, 1390/12/20

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

1- Tehran University of Medical Sciences 2-Kurdistan University of Medical Sciences

Expected recruitment start date

2012-03-15, 1390/12/25

Expected recruitment end date

2014-03-16, 1392/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of slow-release Methylphenidate on methamphetamine dependence: a double blind and placebo controlled trial

Public title

Slow-release Methylphenidate in the treatment of methamphetamine dependence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosis of Methamphetamine dependence based on DSM-IV-TR ; Positive methamphetamine urinary test at the beginning of the study; age between 18-65 Exclusion Criteria: any other mental disorder on axis I except for depression; Any serious medical or neurological problem ,2- IQ <70; abusing other substances except for nicotine and

methadone; history of Attention Defecit-Hyperactivity Disorder during childhood ; pregnancy and breast feeding; development of psychotic symptoms requirind pharmacotherapy; serious suicidal ideations

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshvarz Blvd

City

Tehran

Postal code

Approval date

2012-02-20, 1390/12/01

Ethics committee reference number

16507

Health conditions studied

1

Description of health condition studied

methamphetamine dependence

ICD-10 code

F11.6

ICD-10 code description

mental and behavioral disorders due to use of other stimulants, dependence syndrome

Primary outcomes

1

Description

craving

Timepoint

Baseline and then weekly

Method of measurement

visual analogue craving scale

2

Description

addiction severity

Timepoint

Baseline and at the end of the study

Method of measurement

by Addiction SeverityIndex

3

Description

rate of use

Timepoint

Baseline and then weekly

Method of measurement

Urinary methamphetamine test

Secondary outcomes

empty

Intervention groups

1

Description

Tablets slow-release methylphenidate 18 mg/day for the first week, 36 mg/day for the second week and then 54 mg/day for remaining 10 weeks

Category

Treatment - Drugs

2

Description

placebo for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods Hospital

Full name of responsible person

Dr. Farzin Rezaei

Street address

No2, Pasdaran Blvd., Qods Hospital, Sanandaj

City
Sanandaj

2

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

South Kargar Sreet, Roozbeh Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Akbar Fotouhi

Street address

Keshvarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Kurdistan University of Medical Sciences

Full name of responsible person

Dr Ataollah Heydari

Street address

No1, Pasdaran Blvd, Kurdistan university of Medical Sciences, Deputy of research, Sanandaj

City

Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kurdistan 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

Tehran University of Medical Sciences

Full name of responsible person

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Position

Prof. of Clinical Psychopharmacology

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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