Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of methylphenidate and modafinil in the reduction of methamphetamine withdrawal symptoms and craving

Protocol summary

Summary

In this double blind study, hospitalized patients with symptoms of methamphetamine withdrawal are selected randomly (odd and even numbers) and allocated in two groups. Each group includes 30 patients. One group will receive methylphenidate and the other group will receive modafinil for two weeks and clinical response will be evaluated every day by interview and questionnaire. The main goal of our study will be comparing the effect of these two drugs on reduction of methamphetamine craving and withdrawal symptoms in order to find the best therapeutic choice.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022025160N2**
Registration date: **2016-05-05, 1395/02/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

Jamshid Ahmadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 3070

Email address

ahmadij@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of methylphenidate and modafinil in the reduction of methamphetamine withdrawal symptoms and craving

Public title

Comparing the effect of methylphenidate and modafinil in the reduction of crystal withdrawal symptoms and craving

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients' age should be between 18 to 50 years; Patients should fill the informed consent form; Methamphetamine is the main substance of abuse.
Exclusion criteria: Patients unwilling to participate at beginning or during the study; Methamphetamine is not the main substance of abuse.

Age

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

Gender

Male

Phase

N/A

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
Not 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 Science, Zand Blvd
City
Shiraz
Postal code
7194634786
Approval date
2016-01-24, 1394/11/04
Ethics committee reference number
IR.SUMS.REC.1394.184

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
craving
Timepoint
daily for 2 weeks
Method of measurement
questionnaire and interview

Secondary outcomes

empty

Intervention groups

1

Description
One group will receive methylphenidate for two weeks
Category
Treatment - Drugs

2

Description
The other group will receive modafinil for two weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebne Sina Hospital
Full name of responsible person
Jamshid Ahmadi M.D.
Street address
Ebne Sina Hospital
City
Shiraz

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
City
Shiraz
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

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Jamshid Ahmadi M.D.

Position
Professor of Psychiatry, Director of Substance Abuse and Mental Health Research Center

Other areas of specialty/work

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Person responsible for updating data

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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