

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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****Street address**

Third floor, Neshat Complex, Daneshjoo Square

**City**

Shiraz

**Postal code**

7194654743

**Phone**

+98 71 3646 1511

**Fax****Email**

jamshid\_ahmadi@yahoo.comajmadij@sums.ac.ir

**Web page address**

sarc.sums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Jamshid Ahmadi M.D.

**Position**

Subspecialist in Substance Abuse

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

Third floor, Neshat Complex, Daneshjoo Square

**City**

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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*