

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A clinical trial on the effect of modafinil in treatment of amphetamine and methamphetamine dependent patients.

Protocol summary

lashkaripour@zaums.ac.ir

Summary

The purpose of this study is to assess the effect of modafinil in treatment of amphetamine and methamphetamine dependent patients in a double blinded clinical trial using placebo in a 12 weeks period. In this study 50 male with the diagnosis of dependency to amphetamine by the DSMIV-TR and no contraindication for using modafinil were chosen and randomly divided into two groups. The first group underwent a treatment with modafinil (200mg daily) for 12 weeks and the second group received only placebo. The desire for consuming methamphetamine was measure by visual analogue scale and also methamphetamine urine test, weekly.

Recruitment status

Recruitment complete

Funding source

Research center of Zahedan University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2016-01-05, 1394/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090219009N1**

Registration date: **2015-11-01, 1394/08/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-01, 1394/08/10

Registrant information

Name

Maryam Lashkaripour

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3342 6572

Email address

Scientific title

A clinical trial on the effect of modafinil in treatment of amphetamine and methamphetamine dependent patients.

Public title

modafinil in treatment of crystal dependency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: male gender ;eighteen to sixty five years old ;Methamphetamine dependency approved by DMSIV-TR criteria ; Positive urine test for amphetamine and methamphetamine ; Having no contraindication for the use of modafinil Exclusion criteria: consuming different kind of drugs except for nicotine and methadone ; No history of psychiatric disorders ; Having medical conditions that may interfere with using modafinil ; Having suicidal thoughts and aggression ; Participating in another study simultaneously ; Quitting the current study

Age

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

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Patients based on randomized method and algorithmic blocks divided into two groups.

Secondary Ids

empty

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

Ethics committee of Zahedan University of Medical Sciences.

Street address

University of Medical Sciences, Persian Gulf Blvd., Zahedan, Sistan and Baluchistan, Islamic Republic Of Iran.

City

Zahedan

Postal code

9816743463

Approval date

2014-06-22, 1393/04/01

Ethics committee reference number

6755

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

Amphetamine-Methamphetamine Dependency

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**

measure of craving

Timepoint

At the onset of the study and then weekly

Method of measurement

visual analogue of craving score

2**Description**

Measuring the severity of dependency

Timepoint

At the onset of the study and then weeks 6th and 12th

Method of measurement

Dependency severity index

3**Description**

Measuring the severity of depression

Timepoint

At the onset of the study and then weeks 6th and 12th

Method of measurement

Beck's Depression Inventory

4**Description**

Measuring the aggression severity

Timepoint

At the onset of the study and then weeks 6th and 12th

Method of measurement

Aggressive questionnaire (AGQ)

Secondary outcomes

empty

Intervention groups**1****Description**

Two hundred milligrams of modafinil manufactured in Tolid Daroo Factory © taking orally per day for 12 weeks.

Category

Treatment - Drugs

2**Description**

Placebo made in the Pharmacology college of Zabol medical university of medical sciences taking orally per day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharan's Psychiatry and Mental Health Hospital

Full name of responsible person

Amir Adibi

Street address

Baharan's Psychiatry and Mental health Hospital,
Imam Khomeini Ave., Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University Of Medical Sciences

Full name of responsible person

Hooshang Rafighdoost

Street address

Research center of Zahedan University of Medical
Sciences, University of Medical Sciences, Persian Gulf
Blvd., Zahedan, Sistan and Baluchistan, Islamic
Republic Of Iran

City

Zahedan

Grant name

125401

Grant code / Reference number

10506

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

Yes

Title of funding source

Zahedan 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

Medical College

Full name of responsible person

Amir Adibi

Position

Resident of Psychiatry

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

Baharan's Psychiatry and Mental health Hospital,
Imam Khomeini Ave., Zahedan

City

Zahedan

Postal code

9819713977

Phone

+98 54 3351 3777

Fax**Email**

amir771155@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University Of Medical Sciences

Full name of responsible person

Maryam Lashkaripour

Position

Associated Professor in Psychiatry

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

Baharan's Psychiatry and Mental health Hospital,
Imam Khomeini Ave., Zahedan

City

Zahedan

Postal code

9819713977

Phone

+98 54 3352 2636

Fax**Email**

dr_lashkaripour@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Lashkaripour

Position

Faculty of Medical College/Associated Professor of
Psychiatry

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

Baharan's Psychiatry and Mental health Hospital,
Imam Khomeini Ave., Zahedan

City

Zahedan

Postal code

9817669749

Phone

+98 54 3342 5672

Fax**Email**

dr_lashkaripour@yahoo.com

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty