Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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 bye the DSMIV-TR and no contraindication for using modafilin 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.

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

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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

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

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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

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Person responsible for scientific inquiries

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Associated Professor in Psychiatry

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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