

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effectiveness of Modafinil with placebo on sleep of patients diagnosed with methamphetamine dependency

Protocol summary

Study aim

the effect of Modafinil on sleep pattern in methamphetamine withdrawal

Design

the double-blinded randomized controlled study with control group, With parallel groups, sample size was 80 patients

Settings and conduct

study was done on patients were referred to psychiatry Hospital, Sari, Iran and treated with modafinil (200mg/day). Pittsburgh sleep quality index and Epworth sleepiness scale were used to assess sleep pattern in 1th and 56th day of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria were eighteen to sixty five years of age, recent methamphetamine dependency based ,continue to attend the study until the end, male gender. Exclusion criteria were abuse of different kinds of drugs along with methamphetamine simultaneously, The presence of a significant physical illness such as serious coronary, liver disease, uncontrolled diabetes, uncontrolled hypertension and increased liver enzymes more than three time normal before the entrance to the study, having suicidal thoughts or recent suicide attempt

Intervention groups

The intervention group received 200 mg of modafinil daily by the end of the week eight. The control group received 200 mg of placebo per day by the end of week eight. Psychiatric interview was conducted for all patients. Patients were not aware of the type of medicine (modafinil/placebo). This study was designed to evaluate the effect of modafinil on improving the sleep pattern of methamphetamine withdrawal or its possible complications.

Main outcome variables

methamphetamine withdrawal; recurrence; sleep pattern

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181218042036N1**

Registration date: **2019-03-16, 1397/12/25**

Registration timing: **retrospective**

Last update: **2019-03-16, 1397/12/25**

Update count: **0**

Registration date

2019-03-16, 1397/12/25

Registrant information

Name

fatemeh Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 3104

Email address

f.amini@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2018-10-07, 1397/07/15

Actual recruitment start date

2018-09-06, 1397/06/15

Actual recruitment end date

2018-09-30, 1397/07/08

Trial completion date

2018-11-11, 1397/08/20

Scientific title

Comparison of the effectiveness of Modafinil with placebo on sleep of patients diagnosed with methamphetamine dependency

Public title

Modafinil effect on sleep of patient with methamphetamine dependency

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

eighteen to sixty five years of age recently methamphetamine dependency based on the diagnostic and statistical manual of mental disorders, 5th edition, text revision (DSM-5) and SCID criteria methamphetamine dependency based on the diagnostic and statistical manual of mental disorders, 5th edition, text revision (DSM-5) and SCID criteria The desire to attend this study Continuation of the study until the end

Exclusion criteria:

The presence of a significant physical illness such as serious coronary, liver disease, uncontrolled diabetes, uncontrolled hypertension and increased liver enzymes more than three time normal significant neurologic or psychiatric primary illness based on SCID by a psychiatrist, having suicidal thoughts and aggression

Age

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

Gender

Male

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **77**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients have randomized in 20 blocks (4 patients per block) into intervention and control group using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization was performed by an independent person, who was not involved elsewhere in the trial. Participants did not know the type of medicine used (modafinil / placebo). Clinical care did not know the type of medicine used (modafinil / placebo). Investigator of the outcome did not know the type of medicine used (modafinil / placebo). The data analyst did not know the type of medicine used (modafinil / placebo). Concealment of allocation was performed using sequentially numbered, sealed, opaque and stapled envelopes. Separate people were responsible for generation of

randomization codes, treatment allocation and interviewing. The patients, research investigators and interviewers were all blinded to the treatment allocation. Modafinil and placebo were completely identical in their size, color, shape, texture and odor.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Moalem Street

City

Sari

Province

Mazandaran

Postal code

4815838531

Approval date

2018-06-18, 1397/03/28

Ethics committee reference number

IR.MAZUMS.REC.1397.163

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

sleep

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Sleep pattern

Timepoint

in 1th and 56th day of the study

Method of measurement

Pittsburgh sleep quality index (PSQI) and Epworth sleepiness scale (ESS) were used to assess sleep pattern

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants started 100 mg of modafinil by a day. Psychiatric interview was done for all patients according to DSM-5 and SCID. Prescriptive modafinil used from Sobhan pharmaceutical company in Iran.

Category

Treatment - Drugs

2

Description

Control group: The participants started 100 mg of placebo by a day and after three days, they received 200 mg of placebo by a day until the end of week 8. Psychiatric interview was done for all patients according to DSM-5 and SCID. Prescriptive placebo used from Sobhan pharmaceutical company in Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Psychiatry Hospital, Sari, Iran

Full name of responsible person

Fatemeh Amini

Street address

Pasdaran Boulevard

City

Sari

Province

Mazandaran

Postal code

4815838531

Phone

+98 11 3334 3104

Email

Amini.Fatemeh2000@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeidi

Street address

Moalem Street

City

Sari

Province

Mazandaran

Postal code

4843185774

Phone

+98 11 3327 3024

Email

pbs.researchcenter@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

fatemeh Amini

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Pasdaran Boulevard

City

Sari

Province

Mazandaran

Postal code

4815838531

Phone

+98 33343104

Email

f.amini@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Amini

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

clinical psychology

Street address

Sarv Ave., Rafi St., Pasdaran Blvd., Sari Town

City

Sari

Province

Mazandaran

Postal code

4815838531

Phone

+98 11 3334 3104

Email

f.amini@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Amini

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Pasdaran Boulevard

City

Sari

Province

Mazandaran

Postal code

4815848531

Phone

+98 11 3334 3104

Email

F.amini@mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Dissatisfaction of the participants in the study

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

the clinical study report will be presented in a clear paper

When the data will become available and for how long

The documentation will be submitted within 6 months

To whom data/document is available

Due to informed consent and initial contract, participants didn't allow the public to access their questionnaires

Under which criteria data/document could be used

Due to informed consent and initial contract, participants didn't allow the public to access their questionnaires

From where data/document is obtainable

Due to informed consent and initial contract, participants didn't allow the public to access their questionnaires

What processes are involved for a request to access data/document

Due to informed consent and initial contract, participants didn't allow the public to access their questionnaires

Comments